

Cumulative radiation exposure during thoracic endovascular aneurysm repair and subsequent follow-up[†]

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Abstract

OBJECTIVES: Thoracic endovascular aneurysm repair (TEVAR) is an appealing alternative to the standard surgical approach, but requires rigorous radiological follow-up. The cumulative radiation exposure (RE) of patients undergoing TEVAR—including pre-operative workup, the procedure and subsequent follow-up computed tomography (CT) imaging—has not previously been investigated.

METHODS: From August 2003 to February 2011, 48 patients underwent TEVAR at our institution. Mean age was 66 ± 11 years, with 10 patients (21%) aged <60 years. Forty-one (85%) patients were male; 7 (15%) had urgent/emergent operation; 21 (44%) had undergone previous aortic surgery. Mean aortic diameter was 7.3 ± 2.1 cm. Intra-operative screening time and RE were reviewed, and typical institutional thoracic CT scan RE was calculated (17.8 mSv). Life expectancy of an age- and sex-matched population was estimated to assess the cumulative RE from recurrent CT follow-up.

RESULTS: The average screening time was 15.7 ± 11.4 min, with an RE of 11.3 ± 9 mSv. Obese patients had significantly higher RE during TEVAR (Pearson's coefficient = 0.388, $P = 0.019$). The RE dropped from 14.9 ± 9.4 mSv to 8.6 ± 7.9 mSv ($P = 0.033$) after a hybrid suite was established. Our institutional TEVAR protocol involves one pre-operative thoracoabdominal CT scan and three follow-up thoracic CT scans for the first year, with a yearly evaluation thereafter. The life expectancy of an age- and sex-matched population was 17 years. A patient adhering to our surveillance protocol would be subjected to an overall exposure of 89 mSv at 1 year and 161 mSv at 5 years, with a projected lifetime RE >350 mSv.

CONCLUSIONS: A 2-year RE exceeding the threshold of 100 mSv with a life expectancy >15 years can be estimated to lead to a lifetime risk increase in radiation-induced leukaemia and solid-tumour cancer >2.7%. The risks of cumulative RE especially in younger and/or obese patients must be balanced with the expected morbidity and mortality reduction in TEVAR versus traditional open repair, and the anticipated benefits of recurrent radiographic imaging.

Keywords: TEVAR • Radiation exposure • Recurrent CT scan • Radiation-induced cancer

INTRODUCTION

Endovascular repair of descending thoracic aortic aneurysms (TEVAR) is an appealing alternative to the standard surgical approach in these often old and frail patients. In high-volume centres, the results of open repair in terms of mortality and morbidity can be regarded as respectable, considering the natural history of the disease [1, 2], but the overall burden of surgery cannot be disregarded. The benefits of TEVAR to the patient are most apparent in the immediate aftermath of the procedure, with a reduction in 30-day operative mortality, a reduction in peri-operative blood loss, and a shorter procedure time and Intensive Care Unit stay [3, 4]. For particular

indications, such as chronic type B dissection [5], surgery is superior in the long term, offering extremely low re-intervention and re-operation rates, while the results of 'on-label' application for isolated thoracic aortic aneurysm repair appear highly encouraging [6].

Despite the appealing short-term results re-operation may prove to be Achilles' heel of TEVAR, with percentages of freedom from re-intervention at 48 months being as low as 81% [7]. Therefore, the patient is not only exposed to a risk of short-term adverse effects of radiation exposure (RE) from the procedure itself—admittedly very low—but to the consequences of further radiation during the rigorous radiological follow-up which is mandatory after TEVAR. Manufacturer's recommendations underline the importance of strict life-long surveillance: regular and consistent follow-up is considered a critical part of ensuring the effectiveness of TEVAR.

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Medical X-rays have been the largest man-made source of population exposure to ionizing radiation, particularly with the use of computed tomography (CT), which has led to a rapid increase in the number of relatively high-dose X-ray examinations performed. The adverse effects of very low-dose RE are still debated, but extensive studies of the mortality of atomic bomb survivors leave little doubt that a cumulative RE exceeding 100 mSv can increase the lifetime risks of radiation-induced cancers [8, 9].

The cumulative RE of patients undergoing TEVAR—including the pre-operative workup, the procedure and recurrent follow-up computed tomographic imaging—has not previously been investigated.

METHODS

Patient demographics

A review of our institutional database disclosed 48 consecutive patients who underwent endovascular repair of thoracic aortic aneurysm from August 2003 to February 2011. An individual patient consent was not required for this retrospective research.

Table 1 summarizes the demographics and clinical characteristics of the entire cohort of patients. Mean age was 66.5 ± 11.2

years (median: 70; range: 28–80 years); 21% (10) of the patients were younger than 60 years; 41 patients were male (85%). Thirty-five patients were hypertensive (73%), and 12 had a coronary artery disease. None of the patients presented with end-stage renal disease requiring haemodialysis, but 12 (25%) had a slight renal insufficiency with an average pre-operative serum creatinine level of 1.5 ± 0.3 mg/dl. Overweight was quite a common feature of this cohort: 67% had a body mass index (BMI) exceeding 25 kg/m^2 , recommended as the upper limit of normal by the World Health Organization (WHO) [10], with the average BMI 27 ± 4.2 ; the median was 26.7 (range: 20.3–37.6).

The average size of the descending or thoracoabdominal aorta at the time of the procedure was 73 ± 21 mm (median: 66; range: 52–120). Twenty-one patients (44%) had undergone an aortic procedure prior to the current TEVAR, most commonly open repair of abdominal aortic aneurysm (AAA) (nine patients). In seven cases (15%), an urgent/emergent procedure was required.

Radiological equipment and institutional TEVAR protocol

Endovascular procedures were performed in a designated operating room equipped with a carbon fibre table until 2008; images were obtained with an OEC 9800 Plus and a OEC 9900 Elite portable C-arm with a 12-inch image intensifier (GE Healthcare, Salt Lake City, UT, USA). In 2008, a full hybrid operating room was built and equipped with an eight-way motorized tabletop and a ceiling-mounted interventional imaging system (Siemens Artis zee, Siemens Ag Medical Solutions, Erlangen, Germany) featuring a 20×20 flat detector, enabling flexible positioning around the patient.

A 16-slice CT scanner was initially used in our Radiology Department, but replaced in 2005 by a 64-slice CT scanner acquired by our Institution. From January 2010 all the exams were performed with a Discovery CT750 HD (GE Healthcare, Milwaukee, WI, USA) with ASiR™ (Adaptive Statistical Iterative Reconstruction) a reconstruction technology that enables reduction of patient radiation dose up to 40%.

The institutional TEVAR protocol was shaped over the years according to the recommendations of the manufacturers and intervening national and international guidelines. The pre-operative work-up includes a thoracoabdominal CT scan (contrast and non-contrast) for thorough measurements and evaluation of aorto-iliac calcification, diameter and tortuosity, and also anteroposterior and lateral chest radiographs. The angiogram suggested by some manufacturers was never part of our routine. The imaging schedule for proper follow-up requires a thoracic CT scan (contrast and non-contrast) and an AP and lateral chest radiograph (to assess the structural integrity of the device, the presence of fractures or component separation) at 1, 6, 12 months and annually thereafter.

Data collection and radiation dose calculation

The screening time (expressed in min) and the total dose-area product accumulated over the entire procedure (DAP, expressed in Gycm^2) were obtained from the operating room register, which is filled in by a certified radiology technician. The DAP is

Table 1: Patient demographics and clinical risk profiles for the entire cohort ($n = 48$)

	n (%)
Sex	
Male	41 (85.4)
Female	7 (14.6)
Age (years)	
Mean \pm SD	66.4 ± 11.2
Median (range)	70 (28–80)
Weight (kg)	
Mean \pm SD	78.8 ± 13.7
Median (range)	75 (59–119)
Height (m)	
Mean \pm SD	1.72 ± 0.08
Median (range)	1.7 (1.54–1.98)
BMI (kg/m^2)	
Mean \pm SD	26.74 ± 4.15
Median (range)	26.7 (20.3–37.56)
BSA DuBois (m^2)	
Mean \pm SD	1.91 ± 0.17
Median (range)	1.88 (1.6–2.34)
Marfan syndrome	2 (4.2)
COPD	7 (14.6)
CAD	12 (25)
Requiring previous CABG or stent	8
EF % (mean \pm SD)	59.5 ± 10.5
Hypertension	35 (72.9)
IDDM	10 (20.8)
Chronic renal insufficiency	12 (25)
Previous vascular intervention	22 (45.8)
Open surgery	14
Endovascular	8

COPD: chronic obstructive pulmonary disease; CAD: coronary artery disease; CABG: coronary artery bypass graft; IDDM: insulin-dependent diabetes mellitus.

the integral of the absorbed dose to air over the area of the X-ray beam in the plane perpendicular to the beam axis, and is recorded by a DAP meter mounted on the X-ray tube between the diaphragms that control the beam size and the patient.

The radiation burden of a thoracic CT scan performed during the study period at our institution was calculated by averaging the dose-length product (DLP, expressed in mGycm) of each follow-up scan. This was deemed to offer a reasonable degree of accuracy, considering the relevant interpatient variability. The pre-operative CT scan, which usually included the abdominal segment, was analysed separately to avoid an overestimation of the total radiation dose.

The average entrance skin dose (expressed in mGy) for posteroanterior and lateral chest radiographs was derived from the literature [11].

The RE of TEVAR, chest radiography and CT scan were finally calculated by using three different multiplication conversion factors (0.20 mSv/Gycm², 0.18 mSv/mGy and 0.017 mSv/mGycm, respectively), obtaining an effective dose equivalent expressed in mSv [12, 13]. The effective dose is defined as the weighted sum of the mean doses to a number of radiosensitive tissues or organs in the body, and essentially takes account of non-uniform body exposures and the organs and tissues known to be sensitive to deleterious radiation effects. The conversion of all measurements to mSv facilitates comparisons with similar procedures, and allows cumulative calculations.

Life expectancy assessment

To assess the overall life expectancy of the entire cohort, the life tables provided by the Italian Institute of Statistics (ISTAT) were reviewed. The median year of the endovascular procedure (2007) was calculated to select the proper ISTAT life tables. Separate estimations for the 41 males and the 7 females were carried out to obtain the age- and sex-matched life expectancy.

Statistical methods

Data were entered into Excel spreadsheets and transferred to a SAS file for description and analysis. Patient and disease characteristics are described as per cents, median (range) or means (standard deviation), as well as the average screening time, radiation dose and amount of intravenous contrast. To evaluate the strength of linear dependence between BMI and RE, scatter plots were constructed and corresponding Pearson correlation coefficients (*r* values) were calculated. The statistical significance of *r* was tested using a *t*-test. Continuous variables were compared using unpaired Student's *t*-tests to analyse differences between the two groups.

RESULTS

Clinical outcomes

Overall hospital mortality, defined as death in the hospital during recovery from the endovascular procedure or within 30 days after operation, was 10.4% (five patients); there were no intra-operative deaths. In the vast majority of the cases, there was no need for a hybrid procedure, since the anatomical

features allowed optimal proximal and distal sealing. In seven cases, an adequate proximal landing zone could not be identified, and aortic debranching was performed to allow an effective TEVAR to be performed. Hospital mortality for TEVAR without debranching was 4.9% (two patients). The subclavian artery was intentionally covered 14 times (29.2%); surgical re-implantation was never carried out since symptoms related to vessel occlusion were not observed.

A total of 76 stent grafts were implanted: an average of 1.6 ± 0.8 per patient (median: 1, range: 1–4). A variety of devices were utilized, most commonly Gore TAG and C TAG (W. L. Gore Associates, Flagstaff, AZ, USA) (*n* = 23; 28%); COOK TX1 and TX2 (Cook Medical, Inc., Bloomington, IN, USA) (*n* = 21; 26%) and Medtronic Valiant (Medtronic, Inc., Santa Rosa, CA, USA) (*n* = 21; 26%). The mean aortic length covered was 198 ± 75 mm, ranging from 100 to 290 mm. The average number of segmental artery pairs sacrificed in the entire cohort was 5.8 ± 2.3, with a median of 6 (range: 2–9). All the patients fell into Mount Sinai group A or B (1)–sacrifice of fewer than 13 segmental arteries with coverage beginning in the upper thorax—with an expected spinal cord injury rate <1.5%. In fact, there were no cases of paraplegia or paraparesis.

Radiation exposure during TEVAR

The mean screening time during TEVAR was 15.7 ± 11.4 min (median: 12.3, range: 5.5–54.6). The total DAP accumulated over the complete procedure was 56.7 ± 45.2 Gycm², ranging from 1.4 to 185.5 Gycm² (median: 41.3 Gycm²). The RE of a complete TEVAR procedure could be calculated as 11.3 ± 9 mSv (median: 8.26, range: 0.28–37), using the conversion factor of 0.20 mSv/Gycm². The average amount of intravenous contrast injected during the procedure was 272.5 ± 153.2 ml (median: 230, range: 99–325).

The RE was significantly reduced after the portable C-arm was replaced by a better-performing ceiling-mounted interventional imaging system. The RE dropped from 14.9 ± 9.4 to 8.6 ± 7.9 mSv (*P* = 0.033), while the average screening time and intravenous contrast were only marginally reduced with the new equipment (from 17.6 ± 11.4 min to 14.5 ± 11.5 min, *P* = 0.451; from 321.1 ± 148.4 to 228.8 ± 151.2 ml, *P* = 0.198).

Patients with a high BMI showed a tendency to have higher DAP (and subsequently a higher RE) during TEVAR. Obese patients (BMI >30 kg/m²) were exposed during TEVAR to a dose of ionizing radiation 72% greater than patients with a normal BMI (16.9 ± 12.5 versus 9.8 ± 7.5, *P* = 0.05). A scatter plot showing the correlation between BMI and the effective radiation dose during TEVAR was constructed (Fig. 1). An analysis performed using Pearson's correlation coefficient indicated a statistically significant linear relationship between BMI and RE (*r* = 0.388, *P* = 0.019).

Cumulative radiation exposure

Posteroanterior and lateral chest radiographs exposed the patient to an effective dose of 0.06 mSv. The average thoracic and thoracoabdominal CT scan DLPs were 1049.7 ± 646.8 and 1427 ± 550.5 mGycm, respectively. The use of a multiplication conversion factor of 0.017 mSv/mGycm allowed us to calculate an average RE of 17.8 mSv for a thoracic CT scan, and 24.3 mSv for a thoracoabdominal CT scan.

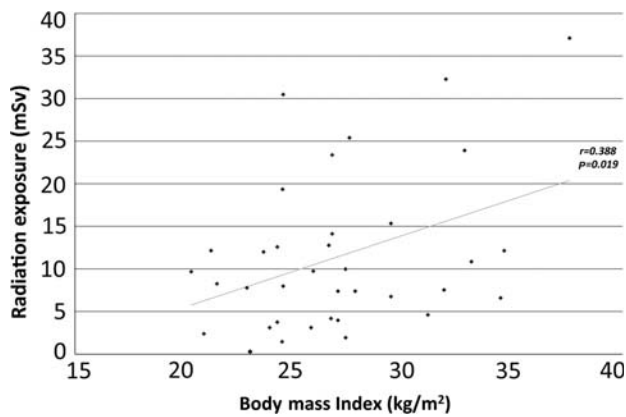


Figure 1: Scatterplot showing the correlation between body mass index and the effective dose during a TEVAR procedure. A trend line with the corresponding Pearson coefficient (r) and significance value (p) is depicted.

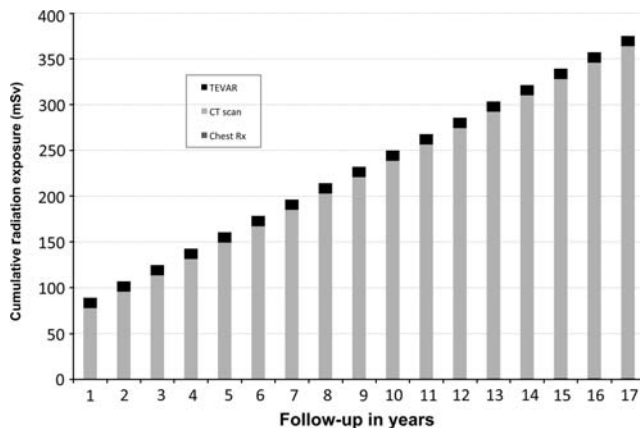


Figure 2: Stacked histogram depicting the cumulative radiation exposure of a patient undergoing a TEVAR procedure and adhering to the suggested follow-up. The proportional contribution of the three different imaging methods to the cumulative RE is depicted.

Considering the pre-operative work-up (chest radiographs and thoracoabdominal CT scan), the exposure during the procedure, and the follow-up suggested by our Department (CT scan and chest radiographs at 1, 6 and 12 months), an average patient would receive a total of 89.24 mSv during the first year. After the first 12 months, an additional 17.86 mSv per year must be incorporated into the calculation of the total cumulative RE. The cumulative RE of a patient undergoing TEVAR and adhering to the suggested follow-up schedule exceeds the threshold of 100 mSv after 2 years (Fig. 2). The overall life expectancy of the entire cohort was 16.89 years, leading to an expected 5- and 10-year RE of 161 and 250 mSv, respectively, with a projected cumulative lifetime exposure of 375 mSv. The contribution of the recurrent follow-up CT scan imaging to the cumulative RE is paramount, and increases with time, being 87% after 1 year, 92% at 5 years and 96% in a lifetime.

DISCUSSION

Over the last several years, interest in endovascular treatment of vascular disease has been continuously increasing. Minimally

invasive methods are being advocated by both patients and clinicians because of the expected peri-procedural reduction in attrition and shorter hospital stay. The endovascular treatment of thoracic and thoracoabdominal aortic aneurysms is of particular appeal since the standard surgical treatment is still considered a formidable challenge. Given the promising short-term results, a variety of thoracic aortic pathologies, such as penetrating ulcers and traumatic transections, have been treated with minimally invasive methods. TEVAR procedures involve the use of ionizing radiation, and increasing procedural complexity coupled with the need for ongoing radiological surveillance result in the potential for substantial RE and its associated risks. Although RE is an accepted and necessary aspect of modern medical practice, its quantification—and assessment of any negative sequelae—should be undertaken.

Detrimental effects from exposure to radiation can be classified as either deterministic or stochastic. Deterministic effects develop due to cell killing by high-dose radiation, have a predictable dose-related response, and therefore have a specific dose threshold below which the effect does not occur. Stochastic effects, in contrast, are probabilistic in nature: the primary risk is of carcinogenesis. Complex forms of double-strand breaks in DNA are the most biologically important type of lesion induced by ionizing radiation. Attempts by the injured tissue to repair the damaged DNA can be ineffective, and there is evidence that the error-prone repair process is likely responsible for mutations (usually base-pair deletions) leading to tumour-suppressor gene inactivation. An absolute threshold cannot be defined for stochastic effects, although it is quite clear that the incidence increases with the dose.

The most reliable statistics on excess relative risk (ERR) of mortality from leukaemia and solid cancers come from studies of Japanese atomic bomb survivors. A cohort of 120 000 such victims has been studied since 1957, and the results are regularly updated [9]. Even individuals in the low-dose categories, exposed to 5–125 mSv (mean: 34 mSv) and 5–150 mSv (mean: 39 mSv), experienced a significant increase in solid cancer-related mortality (ERR = 0.025, $P = 0.025$). The attributable risk for lower medical doses of radiation was extrapolated from the risk observed in the high total body dose cohorts according to the linear non-threshold theory. Leukaemia was the first cancer to be linked to RE in atomic bomb survivors, and excluding the chronic lymphocytic subtype, is considered to be among the cancers most susceptible to induction by ionizing radiation. Pierce *et al.* [14] estimated that 78 of 176 (44%) of leukaemia deaths among survivors with doses exceeding 0.005 Sv were due to RE.

TEVAR screening times (15.7 ± 11.4 min) and overall RE (11.3 ± 9 mSv) in the study patients compare favourably with reported exposures for endovascular repair of AAA and thoracoabdominal aneurysm (TAAA). The complexity of these procedures, which require several branches to be implanted and different gates to be accessed greatly increases fluoroscopic times (29.4 ± 23.3 min are reported for AAA repair [15], and greater than 80 min for TAAA repair [13]) and corresponding RE. The most common adverse effects of acute RE [peak skin dose (PSD)] are skin erythema, permanent epilation and delayed skin necrosis. The generally accepted threshold of 2 Gy [16] was never reached in our cohort (the maximum PSD was calculated to be 0.56 Gy), but more than half of the patients requiring endovascular TAAA repair had a PSD greater than the level considered safe (average PSD 2.5 Gy).

With regard to stochastic effects, the lifetime attributable cancer mortality risk in a 66-year-old patient (the average age of procedure in our cohort) undergoing an isolated TEVAR can be calculated as 0.06% [17]. Even in a high-volume institution [18], this would result in a single cancer-related death over a 35-year-period attributable to the TEVAR programme. TEVAR alone can therefore be considered reasonably safe for both the patient and the operator, especially if a dedicated hybrid suite is available for the procedure. The more focused beam reduces X-ray scatter, and a variety of dose-reducing programmes (variable fluoro pulse rates, radiation-free collimation and object positioning) available with a ceiling-mounted imaging system, led, in our experience, to a 59% decrease in RE ($P = 0.033$).

It was not an unexpected finding that obese patients received a higher dose of radiation per procedure. Fluoroscopy utilizes low-energy X-ray radiation, which is rapidly attenuated as it passes through tissue. In obese patients, the X-ray beam must penetrate more tissue to reach the image detector. The automatic exposure control detects the low output and increases the radiation dose to obtain an image of adequate quality. In our cohort, this resulted in a significant 72% increase in RE among patients with a BMI $>30 \text{ kg/m}^2$. In our study population, 67% of patients were overweight or obese: this is consistent with the reports of the World Health Organization that the estimated prevalence of overweight and obese patients is rapidly growing in a number of countries worldwide, already exceeding 80% in the USA. When planning endovascular treatment for obese patients, therefore, a high RE should be anticipated, and additional efforts to reduce it should always be made.

The long-term performance of endovascular grafts has not yet been established, and endovascular treatment requires life-long, regular follow-up to assess the health and performance of the graft. The willingness to comply with the required follow-up regimen should be investigated in each patient evaluated for TEVAR. Although CT scanning does not carry risks for deterministic effects such as skin injury, recurrent imaging makes a major contribution to the total cumulative lifetime RE. The lifetime risk attributable to a single thoracic CT scan can be regarded as minimal, but the need for life-long radiological surveillance may pose a more serious threat.

It is important, however, to make a distinction between acute exposures over a very short period and protracted exposures. In general, protracted REs are associated with lower risks than a single acute exposure to the same total dose. A variety of mechanisms can reduce the effect of subsequent exposures after an initial low radiation dose (5–100 mSv). Adaptive responses have been well documented in experimental settings, where exposures to repeated radiation doses induce the expression of genes to repair DNA damage. The first 'priming' exposure may decrease radiosensitivity to subsequent even larger REs, although some data suggest that this induced radioresistance may be transitory, with a protective effect lasting only 48 h, making the adaptive response of limited relevance for repeated low-dose RE over a long interval. The bystander effect that results from the reaction between irradiated cells and nearby non-irradiated cells can also influence dose–response relationships. The correct method for assessing risk from repeated studies, however, is still debated. Much attention has been given to studies of large numbers of radiation workers who were chronically exposed to low radiation doses and statistically significant excess cancer risk and mortality risks for both solid cancers and leukaemia were found in cohorts with a lifetime RE as low as 6.5 mSv [19]. A

meta-analysis of leukaemia risk from protracted exposure to low-dose ionizing radiation found an ERR at 100 mGy of 0.19 (95% CI: 0.07–0.32) [20].

According to the studies of atomic bomb survivors, an acute exposure to 375 mSv (the projected lifetime RE in our study) would result in a 24% increase in solid cancers [21]. This figure, however, is just hypothetical, since it does not take into account the latency period of radiation-induced cancer, the age at exposure, or the possible adaptive responses described above. A more reasonable evaluation of the risk connected with a lifetime RE exceeding 350 mSv is offered by a large study on a cohort of $>30\,000$ patients undergoing recurrent CT imaging [22]. The lifetime attributable risk of developing leukaemia or solid cancer for the top percentile of the cohort (lifetime RE >399 mSv) ranged from 2.7 to 12%, with a calculated lifetime attributable risk for cancer mortality between 1.6 and 6.8%.

Since the average life expectancy of our cohort was 17 years, which exceeds the latency periods for both radiation-induced leukaemia and solid cancer, the risk of recurrent CT imaging associated with TEVAR should not be underestimated. Moreover, endovascular therapy is expanding to include pathologies that are not as age-related as aneurysmal disease. A meta-analysis of patients with endovascular versus open repair for traumatic descending thoracic aortic rupture reported a mean age of 38.8 years [23]. With the increasing availability of a variety of devices, an even further reduction in the average age of patients undergoing TEVAR can be expected. Additionally, TEVAR patients often have other co-morbidities requiring radiological imaging, cardiovascular diseases being by far the most frequent. In our cohort, the additional RE related to coronary artery disease (including cardiac CT scans and percutaneous interventions) was 22 mSv per patient.

There is a growing awareness of the risks connected to an elevated cumulative RE, and changes in medical practice are being made when possible. The European Society for Vascular Surgery (ESVS) recently updated the guidelines for the management of AAAs [24] advising physicians to omit the CT scan performed 6 months after endovascular aneurysm repair in patients with no early endoleak and good component overlap. Duplex ultrasound is the suggested life-long imaging method, and CT scan after the first post-operative year should be reserved for patients in whom stent graft abnormalities or sac enlargement are identified by ultrasound.

Unfortunately, the ESVS follow-up protocol for abdominal aortic graft surveillance cannot be adopted for TEVAR patients: transoesophageal echocardiography provides suboptimal information regarding endoleak presence and flow, and should be reserved for patients in whom renal complications or other factors preclude the use of contrast media. Moreover, magnetic resonance imaging cannot provide any valuable follow-up information after TEVAR because of the artefacts caused by the stainless steel components of many grafts, which obscures adjacent anatomical structures within 20 cm of the device.

The impact of cumulative pre-operative and post-operative CT scanning is of course also a concern in patients with open repair. But with surgical repair, the follow-up examinations are not preceded by the intraprocedural dose of radiation associated with TEVAR. In addition, there is usually somewhat less intensive surveillance for the first year after open repair of a thoracic aneurysm than after TEVAR, since the failure of leaks and the durability of the operation can usually be relied upon, and one is doing the surveillance chiefly to monitor the progression of the

underlying aortic disease rather than the integrity of the repair. In the not infrequent situation in which additional endovascular procedures are required following TEVAR, of course, the difference between endovascular and open repair with regard to RE widens as another intraprocedural dose and period of intensive surveillance are added to the tally RE of the TEVAR patient. The availability of MRI is also an option to reduce RE during follow-up with open repair, unlike TEVAR.

In conclusion, TEVAR has evolved over the years as a viable option to complement traditional treatments for aortic disease. The risk of deterministic effects of the accompanying irradiation seem to be negligible, and the low increase in stochastic effects appears acceptable, even in obese patients, who experience a significant intra-procedural RE increase. The use of a dedicated hybrid suite is an additional measure to reduce patient exposure. The need for life-time CT scan surveillance significantly increases the lifetime attributable risk of cancer incidence and mortality, and must be weighed against the expected reduction in morbidity and mortality of TEVAR versus traditional open repair, and the anticipated benefits of recurrent radiographic imaging, especially in younger patients.

Conflict of interest: none declared.

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APPENDIX. CONFERENCE DISCUSSION

Dr C. Etz (Leipzig, Germany): To my knowledge, this is the first study analysing the procedural radiation burden to be expected during TEVAR and the accumulating radiation exposure over time during the follow-up period. The information you are providing us with is important to both the implanting surgeons and, of course, to the patient who has to live with the consequence of life-long recurrent exposure to ionizing radiation.

This information definitely needs to be part not only of the decision-making process (and should be especially considered when discussing questionable indication for TEVAR particularly in young patients), it also needs to be included in the informed consent, especially in this population of young people.

Your average screening time was 15 minutes with a radiation exposure of 11 mSv, while obese patients had significantly higher exposure, which is to be expected. These numbers are pretty good and way quicker than one would expect for TEVAR, meaning that your centre is experienced, and that significantly longer screening times are to be expected in smaller centres with less extensive experience.

I have two questions for you, two case scenarios. Let's say there is a 30-year-old obese female with a progressive proximal descending thoracic aneurysm, who has heard about TEVAR as a minimally invasive treatment option, and she wants you to treat her. What are you going to tell her?

Dr Zoli: In a very young female who might consider a future pregnancy and in the presence of a reasonable operative risk, I would perform an open repair rather than exposing her to a lifetime of surveillance. The concern of lifelong surveillance is obviously present even if you perform open repair. But in the case of open repair, you are more concerned about, let's say, the downstream aorta rather than to check the integrity of your repair. And, also, there is always the possibility of performing an MRI as the follow-up evaluation. This possibility does not appear yet useable for checking on the majority of TEVAR patients.

Dr Etz: Okay. So the second patient would be about the same age, a 35-year-old male (because we had this discussion in the morning) who is a Marfan patient, whose status is post-acute aortic type A dissection repair. He has a remnant downstream dissection to end somewhere above the

diaphragm and a progressive descending thoracic aneurysm. Also, he has heard about this treatment option, and now he is asking you about your treatment, what can you offer.

Dr Zoli: Our institutional policy is to avoid as much as possible the implantation of stents in patients with collagen disease. So if it is a Marfan patient and there are no extraordinary surgical risks, I will try to do an open repair, especially if there is chronic dissection involved. I remember a paper from the Mount Sinai group evaluating the long-term performance of open repair in chronic type B dissection, and the results were pretty impressive. So, coupling this information with the data that I provided this afternoon, I would perform an open repair.

Dr Etz: Okay. So summarizing all this, lastly, if the life expectancy of the patient exceeds the latency period for both radiation-induced leukaemia and solid cancer, the risk for recurrent CAT scan imaging associated with TEVAR can be neglected, where would you draw the line? What is the age where you say we just go ahead and it does not matter?

Dr Zoli: You raise a very good point. It is extremely difficult for me to provide you with an exact age threshold. In our group, we had a 17-year life expectancy which is pretty long and actually exceeds the average latency period for both leukaemia and solid tumour cancer. So if you ask for me an exact figure, I will say 70 years. Below that, I will strongly consider open repair if the general condition and the co-morbidities are not overwhelming.

Dr Etz: Okay. Would you consider any deviation from the protocol? It is a very strict protocol, and some societies say the six-month scan is not necessary. Would you accept exceptions from that protocol in specific cases or would you say we go biannually after a while?

Dr Zoli: You are absolutely right. The European Society for Vascular Surgery recently updated its guidelines for EVAR, and they advised clinicians to omit the six-month CT scan if at one month there were no stent fractures and no endoleaks. They have the big advantage of having duplex ultrasound as a pretty good method to check for the presence of endoleaks and eventual dilation of aorta. This possibility is obviously not available for thoracic endovascular aneurysm repair. It will be extremely interesting to have studies that can tell us if the six-month CT scan is really necessary, i.e. how many endoleaks there are at six months that needed to be treated. At this point with this information, I will go on and try to draw some conclusions.

Dr B. Zipfel (Berlin, Germany): If there are no questions from the floor, I want to add a comment. This is a very impressive paper reminding us that we have to think about the surveillance protocol after TEVAR. There is an alternative to CT scan. We are using MRI imaging more and more. For this you have to implant stent grafts which are MRI compatible. Then you can switch to MRI for the routine follow-up, after the first post-operative CT scan, especially in these younger patients. The images are not as precise as CT scan, but this is a very good compromise for routine surveillance.

Dr Zoli: This is a very good point. Unfortunately, as you mentioned, not every stent available is actually MRI compatible because of the stainless steel components. But it is extremely useful to at least have a choice in younger patients as we mentioned before.

Dr Zipfel: MRI compatibility is for me one of the criteria when choosing a stent graft.