Monitoring neurointerventional radiation doses using dose tracking software; implications for diagnostic reference level calculation

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1. ABSTRACT

Introduction:

While the benefits of neurointerventional procedures outweigh the risks, there is potential for high radiation exposure. Increasing regulatory requirements require dose monitoring of patients and staff, and justification of aberrant exposures. This paper uses radiation dose tracking software to assess factors which influence neuroradiology radiation doses.

Methods:

Consecutive neurointerventional procedures within a one-year period from November 2014 to November 2015 were retrospectively studied. Dose area product (DAP) was collected using dose-tracking software and clinical data was obtained from a prospectively generated patient treatment database. Data analysis was performed on SPSS software.

Results: Two hundred and sixty-four neurointerventional procedures met the selection criteria. Median dose area product (DAP) for aneurysm procedures was 104.9 Gy-cm^2, 259.4 Gy-cm^2 for arteriovenous malformation embolization procedures, 87 Gy-cm^2 for stroke thrombolysis, and 73.7 Gy-cm^2 for 4-vessel angiography. One hundred and nine aneurysm coiling procedures were further studied. Six significant variables were assessed using stepwise regression analysis to determine effect on DAP. Aneurysm location (anterior circulation vs. posterior circulation) had the single biggest effect ($p = 0.004$).

Conclusion: Neurointerventional procedures produce variable radiation exposures. Anterior and posterior aneurysm coiling procedures should have separate DRLs.

Introduction

Neurointervention is an increasingly common method for treating neurological diseases [1]. Continued technological developments are extending the range and complexity of conditions which neurointerventional radiologists can treat. While there are considerable benefits to having a neurointerventional procedure performed over surgery, risks remain, one of which is the exposure of patients and staff to ionising radiation during the procedure.

Deterministic complications such as skin erythema occur at a threshold dose of 2 Grays (Gy), whereas 7 Gy can cause permanent hair loss [2,3]. Cataract formation is a notable risk as the eyes are exposed to radiation throughout the procedure[2,4]. Staff eye doses are also of concern. The International Commission on Radiological Protection (ICRP) has recently recommended a reduction threshold dose for cataract induction from 2 Gy to 0.5 Gy be instituted. As a result, the dose limit for eye exposure among staff has been reduced from 150mSv to 20mSv over a five year period)[5].

The Euratom 2013/59 directive has also made these recommendations meaning that these limits will become a regulatory requirement by February 2018 [6]. The International Radiation Protection Agency has recognised that these changes will have implications for radiation dose monitoring and anticipate that interventional radiology and cardiology are of greatest likelihood to encounter the impact of these changes [7]. There is concern that based on current work practices that there is potential to exceed these limits [8]. Therefore new regulations could have significant implications for the number and complexity of procedures which an interventionalist can perform, and in turn resource implications for tertiary care health institutions.

Requirements for recording radiation dose, calculation and review of diagnostic reference levels (DRLs) in addition to keeping radiation doses as low as reasonable achievable also have resource implications. There are challenges with current methods of collecting dose related data. In CT it has been noted that many studies are incorrectly registered due to non-uniform procedure coding which results in missing procedural data [9].

The need for more reliable methods of standardized data collection has been addressed through the development of dose tracking software tools [10-13] Furthermore it has been shown that 32% of the performed procedures have incomplete radiation dose estimates or fluoroscopy times recorded when they should have been manually documented at the time of examination [12]. In addition, several methods can be used to measure radiation dose which can impede the optimisation process when doses in two intervention rooms in the same institution cannot be directly compared [12].

Dose tracking software automatically collects procedure-related radiation dose data obviating human input error and in a more efficient manner. Given that these data are now readily available the next challenge for healthcare providers is to use the data to inform decision making processes regarding patient consent, radiation protection standardization and optimisation. The purpose of this study was to correlate radiation dose data gathered using dose tracking software with clinical parameters pertaining to neurointerventional procedures and to determine factors associated with increased radiation exposures. These data were then used to assess how DRLs could be best calculated.

METHODS

Board ethical approval was granted for this retrospective descriptive cohort study performed at a single institution. All neuroradiology procedures were performed in a tertiary referral center by one or both of the two staff neuroradiologists. Aneurysm coiling was performed under general anaesthesia. Neurointerventional procedures conducted during the period of November 2014 and November 2015 and included patients who underwent one of four neurointerventional procedures. These were: (1) four vessel angiogram, (2), aneurysm coiling, (3) arteriovenous malformation embolization, and (4) stroke thrombolysis. An expanded cohort of aneurysm coiling procedures patients treated between November 2014 and September 2016 were included following power analysis to allow accurate subgroup analysis.

We measured radiation dose using Dose Area Product (also known as Kerma Area Product), which is expressed as $mGy.cm^2$. Dose data was collected using a picture archiving and communications system (PACS) (Impax 6.5.3; Afga healthcare, Morstel, Belgium), and the dose tracking software (DoseWatch, General Electric Healthcare, Waukesha, WI, USA). Data were entered onto a Microsoft Office Excel 2010 spreadsheet (Microsoft Corporation, CA, USA). Patient sex, patient age, procedure type, number of exposures, screening time, devices used and time of day were recorded for all procedures. For aneurysm coiling procedures, the following additional parameters: site, size, number of coils used, number and shape of aneurysms. Clinical and procedural data on aneurysm neurovascular treatments was taken from a prospectively gathered data file maintained by a neuroradiologist.

Statistical analysis was performed with Statistical Package for Social Scientists (SPSS) software version 23 (IBM, Armonk, NY) and Prism 7 (GraphPad, San Diego, California). Descriptive statistical tests were used to show the median, mean, maximum and minimum radiation dose for each of the four procedures over a one-year period. Tests for normality of distribution were performed using the D'Agostino and Pearson normality test. Additional descriptive analysis was used to determine average age for each procedure and relationship between procedure and sex.

We performed additional analysis on the 4-vessel angiogram and aneurysm coiling data. Wilcoxon matched pairs signed rank test was used to compare anterior verses posterior aneurysm treatment DAPs. Aneurysm-related variables were analysed using two different statistical tests depending on the number of groups per variable. The Mann-Whitney U test was used for variables with two groups. The Kruskel-Wallis test was used for variables with more than two groups. Variables were found to be significant if the p value was less than 0.05. Significant variables were then analysed using stepwise linear regression to determine which variable had the single biggest effect on radiation dose (DAP).

RESULTS

Two hundred and sixty-four consecutive patients who underwent neurointerventional procedures were eligible for inclusion. Of the 264 procedures, 189 four-vessel angiograms, 59 aneurysm coilings, 10 stroke thrombolysis, and 6 arteriovenous malformation embolization procedures were performed. An additional cohort of 60 consecutive patients who underwent aneurysm coiling procedures was added to the aneurysm group to enable subgroup analysis, forming a cohort of 109 patients in total (table 1).

Overall, 61% of the patients were female and 39% were male. The age of participants ranged 15-82 with an average age of 52.5 years for male patients and 53.9 years for female patients. Procedures distinguished by sex differed substantially. The number of aneurysm coiling procedures performed on women was almost double (1.94x) the number performed on men. In contrast to this, AVM embolization and stroke thrombolysis were performed on men at an increased rate of 5x and 2.3x respectively, compared withnwomen. Over all, women were more likely to undergo both diagnostic and therapeutic procedures.

Radiation Dose

The median DAP for four-vessel angiography was 73,726 mGy.cm2 (3rd quartile: 96,326 mGy.cm^2, interquartile range: 49,011 mGy.cm^2). The median radiation DAP for aneurysm coiling was 100,431 mGy.cm^2 (3rd quartile: 122,945 mGy.cm^2, interquartile range: 49,336). The median radiation DAP for arteriovenous malformation embolization was 259,403 mGy.cm^2 (3rd quartile: 310118 mGy.cm^2, interquartile range: 204,591 mGy.cm2). The median radiation DAP for stroke thrombolysis was 87,004 mGy.cm^2 (3rd quartile: 172,261, interquartile range: 125,017 mGy.cm^2 (Table 2).

Figure 1 demonstrates the range of radiation doses for each procedure type. A number of outliers occurred in the aneurysm coiling and four-vessel angiogram groups. These cases were reviewed to determine causes for the increased doses. Three out of the four, four-vessel angiogram outlier cases had an arteriovenous malformation. Two of the six aneurysm coiling procedure outliers were for posterior circulation aneurysm procedures, one of which had an intraoperative complication. Three of the remaining cases had anterior circulation aneurysms that developed complications during the procedure. Nine aneurysm-related variables were found to have a significant effect on DAP (Table 3). The first six variables listed in table 3 were chosen for further analysis (the three other variables involved treatment of a second aneurysm on the same procedure date). Stepwise regression was performed on these variables to determine which variable had the single biggest effect on radiation dose. Aneurysm location was found to have the single greatest affect on radiation dose (p-value = .004) (Tables 4 and 5).

Given the affect that aneurysm location had on radiation dose separate DRLs for the anterior and posterior aneurysm coiling procedures were calculated. The median DAP and 3rd quartiles for anterior circulation aneurysms were 97,824 mGy.cm^2 and 119,290 mGy.cm^2, respectively, while posterior circulation aneurysm treatment resulted in a median

DAP of 127,160 mGy.cm^2 and a 3rd quartile DAP of 151,475 mGy.cm^2. These differences were statistically significant ($p = 0.0005$) (Fig. 3).

Discussion

The calculation and monitoring of DRLs for high dose medical examinations such as neurointerventional procedures is an important component of the Eurotaom BSS directive [i]. The 75th percentile (third quartile) of the spread of the median doses is considered an appropriate DRL estimate. This has been used in assessment of neuroradiology procedures to date [14] [15]. Using reference levels in the 75th percentile accommodates the potentially skewed distribution of radiation dose but the creation of useful DRLs requires the inclusion of sufficient data. This can be a challenge for certain neurointerventional procedures, which have a propensity for complexity and high probability of case outliers.

In the present paper dose tracking software provided a resource efficient means of gathering median DAP for each procedure. The following DRL (3rd quartile values) values were calculated: 96,326 mGy.cm^2 for 4-vessel angiogram procedures; and 122,945 mGy.cm^2 for aneurysm coiling procedures. The following DRLs were also calculated: 172,261 mGy.cm^2 for stroke intervention procedures; and 310,118 mGy.cm^2 for AVM embolization, however, the number of procedures performed in these cohorts were small and additional numbers of patients would be added for accuracy. The use of the 75th centile for DRL calculation was confirmed as exclusion of dose outliers in the aneurysm coiling group (due to intraoperative complications) slightly reduced the 3rd quartile to

119,909 mGy.cm^2 (Fig. 2), however, using a Wilcoxon matched-pairs signed rank test, this difference was deemed to be non-significant (P value = 0.97).

The gathering of DAP data not only provides a means of meeting regulatory requirements but can also be used to inform clinicians and radiographers as to expected doses for neurointerventional procedures and to alert them to individual cases that may have higher than expected doses. In our department the dose tracking software has been set to create an alert when the dose exceeds twice the median dose for a particular radiological investigation or procedure. Using the data from dose tracking software, the alert level for 4-vessel angiography was 147,452 mGy.cm^2 and 11 patients out of 189 patients reached this threshold. For aneurysm coiling procedures, 200,862 mGy.cm^2 represented twice the median dose and generated 5 alerts from 109 cases. The issuing of an alert lead to an assessment of case and required justification of the increased dose. Multiple outliers in two procedure types provided cause for review (see Figure 1). Three of the four four-vessel angiogram outliers were performed on patients with an arteriovenous malformation. In these cases increased dose was justified due to the complexity of the vascular deformity, requiring additional views and acquisitions to better visualise feeding any draining vessels and assess for intra-lesional aneurysms [11].

Aneurysm coiling procedure variables

An assessment of procedural factors contributing to increased radiation dose during aneurysm coiling procedures was performed. Two of the six outliers had posterior circulation aneurysms, where as complications including coil and flow diverter device herniation, thrombus formation, and vasospasm occurred in the remaining four procedure outliers. The occurrence of a complication resulted in increased patient radiation dose as additional imaging was required to treat the complication.

Complications were not, however, the main determinant of radiation dose. Regression analysis demonstrated that the location of a patient's aneurysm was the single biggest influence on radiation dose ($p = 0.004$). Aneurysms in the posterior cerebral circulation are more difficult to treat and this entails a higher complication risk compared with anterior circulation aneurysms [16]. Posterior circulation aneurysms also have a higher risk of rupture [17]. The risk of death from rupture of a posterior circulation aneurysm is much higher than rupture of an anterior circulation aneurysm [18]. The use of a Pipeline embolization device (ev3-Covidien, Irvine, California, USA) and use of a stent for aneurysm coiling procedures both increased radiation dose [19]. The use of these devices was associated with increased procedure times and potentially higher complication risk due to unfavourable anatomy. National DRLs exist in many countries for aneurysm coiling procedures. The results of the present paper highlight the need to monitor doses for anterior and posterior circulation aneurysm coiling procedures separately and calculate DRLs for each in turn.

The DAP levels for cerebral angiogram (n=189) documented in the present paper are lower than other published studies (median 73,726 mGy.cm^2, mean 76,024 mGy.cm^2). For example, Aroua et al. [14] calculated a mean DAP for cerebral angiography of 121,000 mGy.cm^2, Alexander et al. [12] calculated a mean DAP of 102,400 mGy.cm^2, and Sanchez et al. [14] calculated a median DAP of 73,000 mGy.cm^2. There are many potential contributors to this including patient selection, operator experience, and equipment dose efficiency. This phenomenon highlights the need for calculation and monitoring of local DRLs within one's own institution. The introduction of new staff and equipment will likely require a reassessment of dose related data to maintain accuracy. Additionally DRLs are intended for reference purposes and it is important to continue to strive towards improved radiation protection practices in order to keep doses as low as reasonable practicable.

The present paper has not included sufficient arteriovenous malformation embolizations and intraarterial thrombolysis cases to facilitate robust analysis. This is a common challenge since such procedures compose a small proportion of neuroradiology procedures [21, 22]. This challenge also makes it more difficult to identify dose outliers. The use of DAP as a surrogate for patient received dose does introduce an inherent inaccuracy into the data as received dose varies depending on multiple factors such as position and distance of the tube relative to the patient as well as the length of time spent in a particular tube position [20]. While it is possible for dose monitoring software to calculate skin dose based on patient location and tube position, these are not readily available and DAP will likely remain the basis for the calculation of DRLs [23].

In conclusion, innovations in interventional radiology have increased treatment capabilities, which have potential to impact radiation doses incurred by patients and staff.

Compliance with regulatory requirements for monitoring of radiation exposures and justification of dose outliers requires a coordinated approach for gathering dose and clinical data. Dose tracking software provides an efficient means of gathering dose related data. The present paper confirms that the 75th centile provides a reasonable DRL value which is not affected by dose outliers. Results also indicate that aneurysm location has the greatest impact on dose related to coiling procedures and that anterior and posterior coiling procedures should have separate DRLs.

REFERENCES

1. Lin N, Cahill KS, Frerichs KU, Friedlander RM, Claus EB. Treatment of ruptured and unruptured cerebral aneurysms in the USA: a paradigm shift. Journal of neurointerventional surgery. 2012 May 1;4(3):182-9.

2. .Miller DL, Balter S, Schueler BA, Wagner LK, Strauss KJ, Vano E. Clinical radiation management for fluoroscopically guided interventional procedures. *Radiology*. 2010;257(2):321-32.

3. Stecker MS, Balter S, Towbin RB, Miller DL, Vano E, Bartal G, et al. Guidelines for patient radiation dose management. *J Vasc Interv Radiol*. 2009;20(7 Suppl):S263-73.

4. Miller DL, Balter S, Cole PE, Lu HT, Berenstein A, Albert R, et al. Radiation doses in interventional radiology procedures: the RAD-IR study: part II: skin dose. *J Vasc Interv Radiol.* 2003;14(8):977-90.

5. Authors on behalf of I, Stewart FA, Akleyev AV, Hauer-Jensen M, Hendry JH, Kleiman NJ, et al. ICRP publication 118: ICRP statement on tissue reactions and early

and late effects of radiation in normal tissues and organs--threshold doses for tissue reactions in a radiation protection context. *Ann ICRP*. 2012;41(1-2):1-322.

6. COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Official Journal of the European Union. 2014;57.

7. Broughton J, Cantone MC, Ginjaume M, Shah B, Czarwinski R. Implications in dosimetry of the implementation of the revised dose limit to the lens of the eye. Radiation protection dosimetry. 2014 Oct 24;164(1-2):70-4.

8. Seals KF, Lee EW, Cagnon CH, Al-Hakim RA, Kee ST. Radiation-induced cataractogenesis: a critical literature review for the interventional radiologist. Cardiovascular and interventional radiology. 2016 Feb 1;39(2):151-60.

9. Kirova G, Georgiev E, Zasheva C, St Georges A. Dose tracking and radiology department management. *Radiation Protection Dosimetry*. 2015;165(1-4):62-6.

10. Kemerink GJ, Frantzen MJ, Oei K, Sluzewski M, van Rooij WJ, Wilmink J, et al. Patient and occupational dose in neurointerventional procedures. *Neuroradiology*. 2002;44(6):522-8.

11. Bor D, Cekirge S, Turkay T, Turan O, Gulay M, Onal E, et al. Patient and staff doses in interventional neuroradiology. *Radiation Protection Dosimetry*. 2005;117(1-3):62-8.

12. Alexander MD, Oliff MC, Olorunsola OG, Brus-Ramer M, Nickoloff EL, Meyers PM. Patient radiation exposure during diagnostic and therapeutic interventional neuroradiology procedures. *Journal of Neurointerventional Surgery*. 2010;2(1):6-10.

13. Sanchez RM, Vano E, Fernandez JM, Moreu M, Lopez-Ibor L. Brain radiation doses to patients in an interventional neuroradiology laboratory. *American Journal of Neuroradiology*. 2014;35(7):1276-80.

14. Aroua A, Rickli H, Stauffer JC, Schnyder P, Trueb PR, Valley JF, et al. How to set up and apply reference levels in fluoroscopy at a national level. *Eur Radiol*. 2007;17(6):1621-33.

15. Miller DL, Balter S, Cole PE, Lu HT, Schueler BA, Geisinger M, et al. Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study Part I: Overall Measures of Dose. *Journal of Vascular and Interventional Radiology*. 2003;14(6):711-27

16. Villablanca JP, Achiriolaie A, Hooshi P, Martin N, Duckwiler G, Jahan R, et al. Aneurysms of the posterior circulation: detection and treatment planning using volume-rendered three-dimensional helical computerized tomography angiography. *J Neurosurg*. 2005;103(6):1018-29.

17. Villablanca JP, Duckwiler GR, Jahan R, Tateshima S, Martin NA, Frazee J, et al. Natural history of asymptomatic unruptured cerebral aneurysms evaluated at CT angiography: growth and rupture incidence and correlation with epidemiologic risk factors. *Radiology*. 2013;269(1):258-65.

18. Schievink WI, Wijdicks EF, Piepgras DG, Chu CP, O'Fallon WM, Whisnant JP. The poor prognosis of ruptured intracranial aneurysms of the posterior circulation. *J Neurosurg*. 1995;82(5):791-5.

19. Fischer S, Vajda Z, Aguilar Perez M, Schmid E, Hopf N, Bazner H, et al. Pipeline embolization device (PED) for neurovascular reconstruction: initial experience in the

treatment of 101 intracranial aneurysms and dissections. *Neuroradiology*. 2012;54(4):369-82.

20. Miller D KD, Bonavia G. Reference Levels of Patient Radiation Doses in Interventional Radiology. *Radiology*. 2009;253(3):753-64.

21. Fleetwood IG, Steinberg GK. Arteriovenous malformations. *Lancet*. 2002;359(9309):863-73.

22. Berman MF, Sciacca RR, Pile-Spellman J, Stapf C, Connolly ES, Jr., Mohr JP, et al. The epidemiology of brain arteriovenous malformations. *Neurosurgery*. 2000;47(2):389-96;

23. Johnson PB, Borrego D, Balter S, Johnson K, Siragusa D, Bolch WE. Skin dose mapping for fluoroscopically guided interventions. Medical physics. 2011 Oct 1;38(10):5490-9.

PROCEDURE

4-Vessel Angiogram	Aneurysm Coiling	AVM Embolisation	Stroke Thrombolysis	Total
189	109	6	10	314

Table 1. Summary of procedures for study.

Dose Area Product (DAP) for neurointerventional procedures		
Procedure	**Measure**	**Statistic**
4-vessel angiogram	Mean	76,024
	Median	73,726
	75% percentile	96,326
	Minimum	9,424
	Maximum	244,134
Aneurysm coiling	Mean	108,021
	Median	100,431
	75% percentile	122,945
	Minimum	42,807
	Maximum	365,841
AVM embolization	Mean	223,852

	Median	259,403
	75% percentile	310,118
	Minimum	74,236
	Maximum	330,935
Stroke thrombolysis	Mean	107368
	Median	87004
	75% percentile	172,261
	Minimum	37,028
	Maximum	191,422

Table 2. Summary of radiation Dose Area Product measurement for interventional procedures. (All values written as $mGy.cm^2$)

Variable	Significance
A1 Pipeline	.037
A1 Stent	.019
A1 Complications	.000
Aneurysm Location	.008
A1 Body Remnant	.035
Aneurysm2	.004
Aneurysm2 Procedure	.020
A2 Coiling	.044
A2 Remodelling	.013

Table 3. Variables affecting DAP for aneurysm coiling procedures: **A1 Pipeline** = use of pipeline device during procedure for aneurysm 1. **A1 Stent** = use of a stent during procedure for aneurysm 1. **A1 Complications** = complications occurred during procedure for aneurysm 1. **Aneurysm Location** = whether aneurysm was present in the posterior cerebral circulation. **A1 Body Remnant** = Raymond-Roy 3. **Aneurysm2** = presence of a second aneurysm. **Aneurysm2 Procedure** = procedure performed on second aneurysm. **Aneurysm2 Coiling** = coiling performed on second aneurysm. **A2 Remodelling** = use of balloon to stabilize coils during second aneurysm procedure

Model		Beta In	t	Sig.	Partial Correlation	Collinearity
						Tolerance
1	A1 Pipeline	.051[b]	.529	.598	.053	.938
	A1 Stent	.002[b]	.023	.982	.002	.979
	A1 Complications	.099[b]	1.047	.298	.104	.999
	A1 Body Remnant	.037[b]	.384	.702	.038	.993
	Aneurysm2	.031[b]	.322	.748	.032	.996

Table 4. Excluded variables on dose following stepwise regression analysis

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	3.596E+11	1	3.596E+11	8.934	.004[b]
	Residual	4.105E+12	102	40248883591		
Total		4.465E+12	103			

Table 5. Aneurysm Location effect on DAP

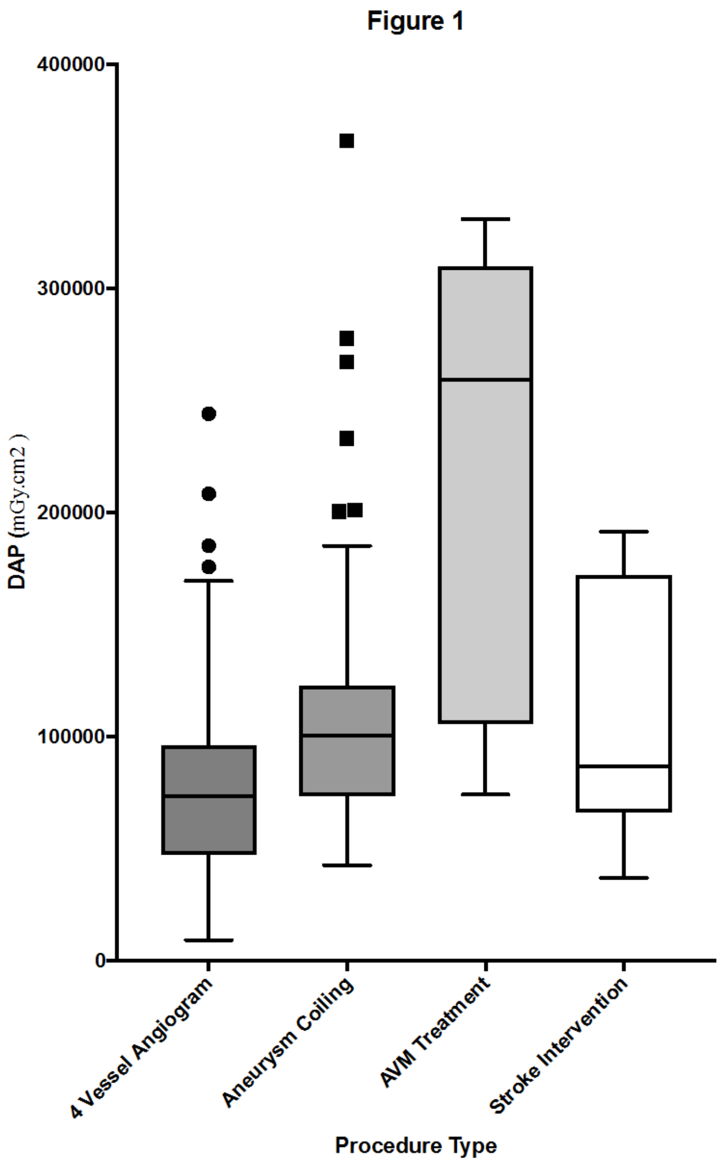

Figure 1: Box and whiskers (Tukey) graph showing median DAP and outliers for the neurovascular procedures analysed

Figure 2

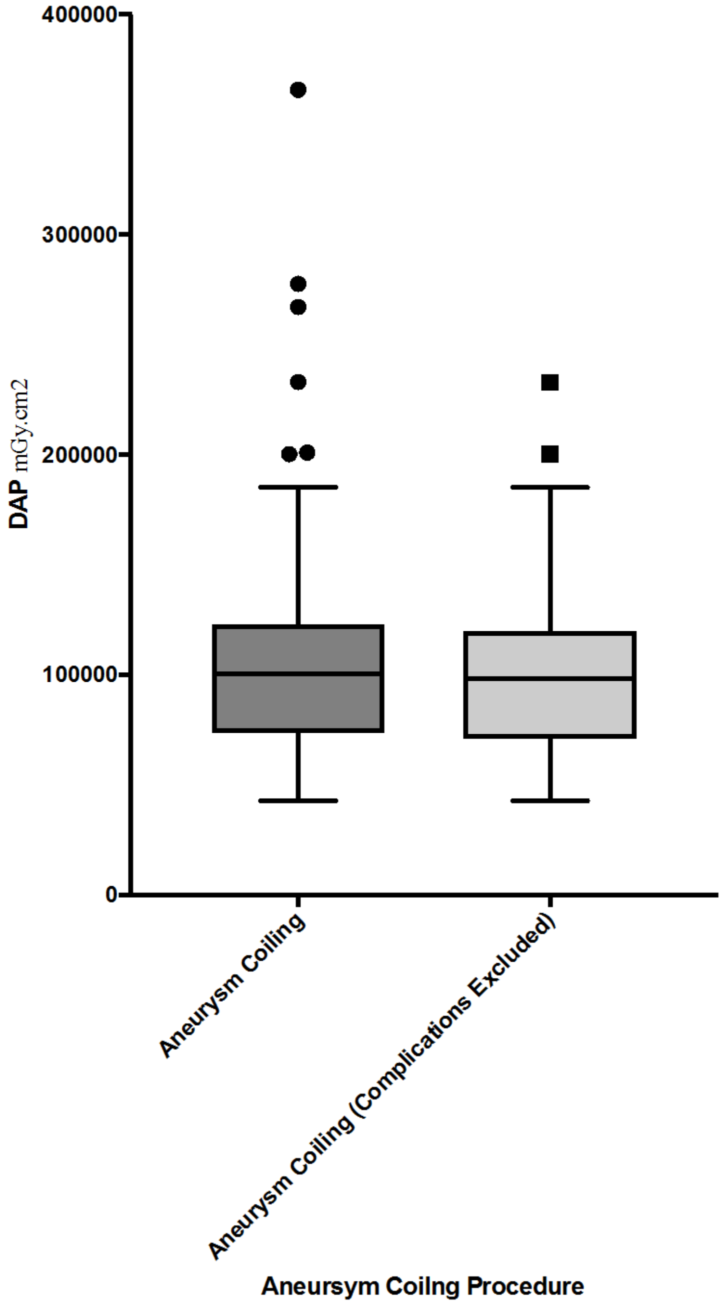

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Figure 2: Box and whiskers (Tukey) graph showing median DAP and outliers for all treated aneurysms (including cases with complications) verses DAP for treated aneurysm cases excluding those with intra-operative complications. ($p = 0.9798$)

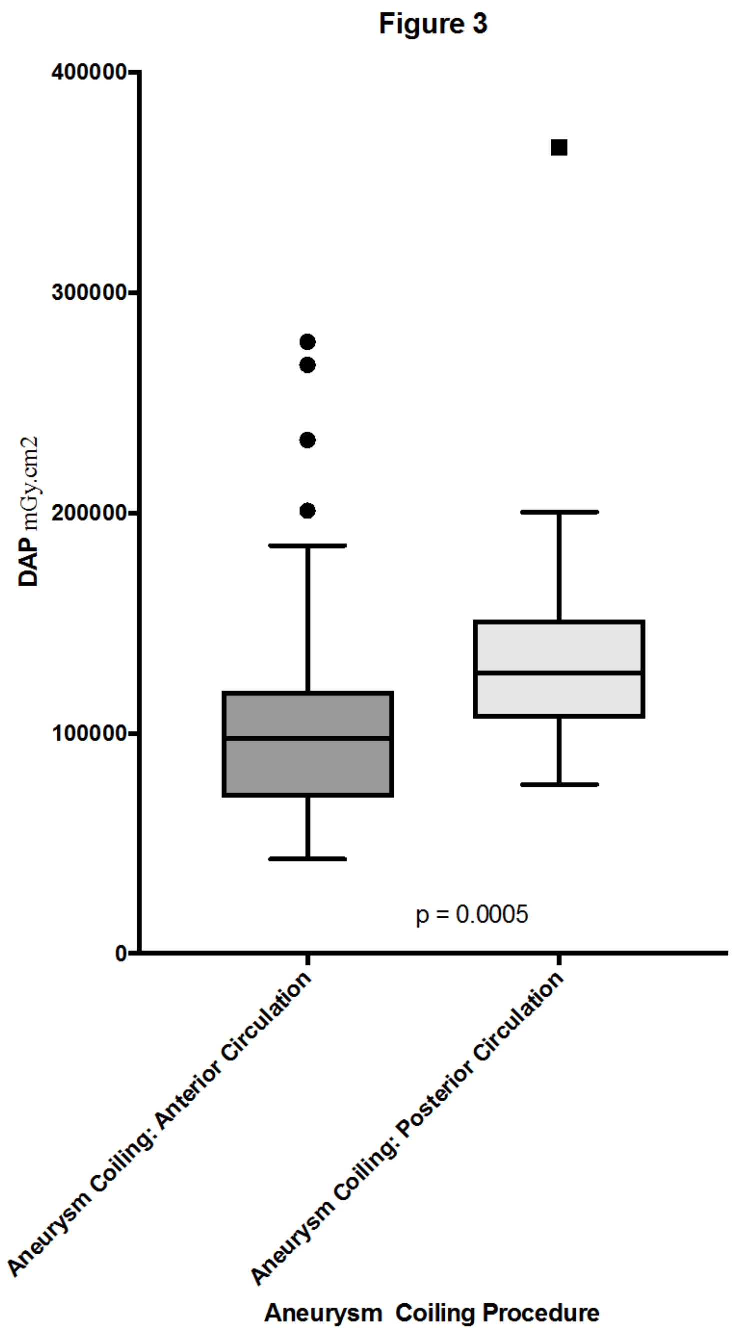

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Figure 3: Box and whiskers (Tukey) graph showing median DAP and outliers for treated anterior aneurysms verses posterior aneurysms (p = 0.0005)

~~[i] 2. Council of the European Union. (2013). Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Official Journal L-13 of 17.01.2014.~~