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**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<sup>2</sup>, 259.4 Gy-cm<sup>2</sup> for arteriovenous malformation embolization procedures, 87 Gy-cm<sup>2</sup> for stroke thrombolysis, and 73.7 Gy-cm<sup>2</sup> 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<sup>[1]</sup>. 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<sup>[2,3]</sup>. Cataract formation is a notable risk as the eyes are exposed to radiation throughout the procedure<sup>[2,4]</sup>. 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<sup>[5]</sup>.

The Euratom 2013/59 directive has also made these recommendations meaning that these limits will become a regulatory requirement by February 2018<sup>[6]</sup>. 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<sup>[7]</sup>. There is concern that based on current work practices that there is potential to exceed these limits<sup>[8]</sup>. 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 <sup>[9]</sup>.

The need for more reliable methods of standardized data collection has been addressed through the development of dose tracking software tools <sup>[10-13]</sup> 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 <sup>[12]</sup>. 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 <sup>[12]</sup>.

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  $\text{mGy}\cdot\text{cm}^2$ . 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 versus 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 Kruskal-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 with women. 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.cm<sup>2</sup> (3<sup>rd</sup> quartile: 96,326 mGy.cm<sup>2</sup>, interquartile range: 49,011 mGy.cm<sup>2</sup>). The median radiation DAP for aneurysm coiling was 100,431 mGy.cm<sup>2</sup> (3<sup>rd</sup> quartile: 122,945 mGy.cm<sup>2</sup>, interquartile range: 49,336). The median radiation DAP for arteriovenous malformation embolization was 259,403 mGy.cm<sup>2</sup> (3<sup>rd</sup> quartile: 310118 mGy.cm<sup>2</sup>, interquartile range: 204,591

mGy.cm<sup>2</sup>). The median radiation DAP for stroke thrombolysis was 87,004 mGy.cm<sup>2</sup> (3<sup>rd</sup> quartile: 172,261, interquartile range: 125,017 mGy.cm<sup>2</sup> (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 3<sup>rd</sup> quartiles for anterior circulation aneurysms were 97,824 mGy.cm<sup>2</sup> and 119,290 mGy.cm<sup>2</sup>, respectively, while posterior circulation aneurysm treatment resulted in a median

DAP of 127,160 mGy.cm<sup>2</sup> and a 3<sup>rd</sup> quartile DAP of 151,475 mGy.cm<sup>2</sup>. 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 Euroatom BSS directive<sup>1</sup>. The 75<sup>th</sup> 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 75<sup>th</sup> 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 (3<sup>rd</sup> quartile values) values were calculated: 96,326 mGy.cm<sup>2</sup> for 4-vessel angiogram procedures; and 122,945 mGy.cm<sup>2</sup> for aneurysm coiling procedures. The following DRLs were also calculated: 172,261 mGy.cm<sup>2</sup> for stroke intervention procedures; and 310,118 mGy.cm<sup>2</sup> 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 75<sup>th</sup> centile for DRL calculation was confirmed as exclusion of dose outliers in the aneurysm coiling group (due to intraoperative complications) slightly reduced the 3<sup>rd</sup> quartile to

119,909 mGy.cm<sup>2</sup> (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<sup>2</sup> and 11 patients out of 189 patients reached this threshold. For aneurysm coiling procedures, 200,862 mGy.cm<sup>2</sup> 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 <sup>[11]</sup>.

#### *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 <sup>[16]</sup>. Posterior circulation aneurysms also have a higher risk of rupture <sup>[17]</sup>. The risk of death from rupture of a posterior circulation aneurysm is much higher than rupture of an anterior circulation aneurysm <sup>[18]</sup>. 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 <sup>[19]</sup>. 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<sup>2</sup>, mean 76,024 mGy.cm<sup>2</sup>). For example, Aroua et al. <sup>[14]</sup> calculated a mean DAP for cerebral angiography of 121,000

mGy.cm<sup>2</sup>, Alexander et al. <sup>[12]</sup> calculated a mean DAP of 102,400 mGy.cm<sup>2</sup>, and Sanchez et al. <sup>[14]</sup> calculated a median DAP of 73,000 mGy.cm<sup>2</sup>. 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 <sup>[21, 22]</sup>. 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 <sup>[20]</sup>. 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 <sup>[23]</sup>.

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 75<sup>th</sup> 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.

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**PROCEDURE**

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

**Table 1.** Summary of procedures for study.

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

	Median	259,403
	75% percentile	310,118
	Minimum	74,236
	Maximum	330,935
<b>Stroke thrombolysis</b>	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<sup>2</sup>)

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

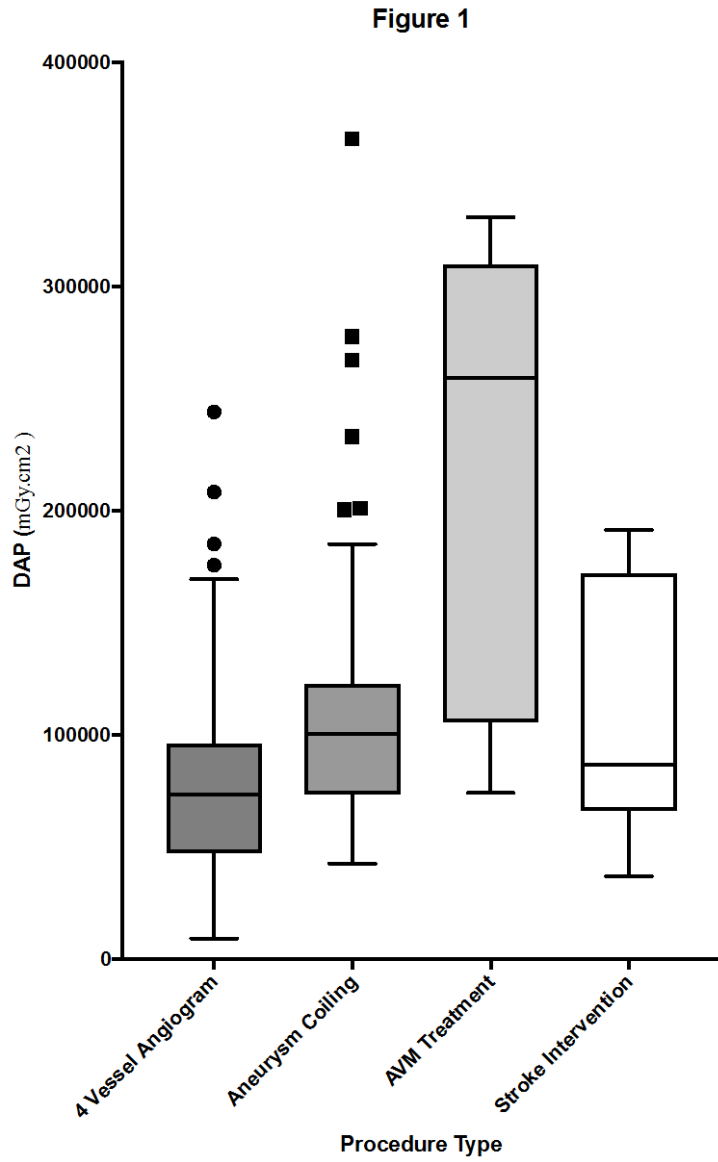
**Table 3.** Variables affecting DAP for aneurysm coiling procedures: **A1 Pipeline** = use of pipeline device during procedure for aneurysm 1. **A1 Stent** = use of a stent during procedure for aneurysm 1. **A1 Complications** = complications occurred during procedure for aneurysm 1. **Aneurysm Location** = 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 <sup>b</sup>	.529	.598	.053	.938
A1 Stent	.002 <sup>b</sup>	.023	.982	.002	.979
A1 Complications	.099 <sup>b</sup>	1.047	.298	.104	.999
A1 Body Remnant	.037 <sup>b</sup>	.384	.702	.038	.993
Aneurysm2	.031 <sup>b</sup>	.322	.748	.032	.996

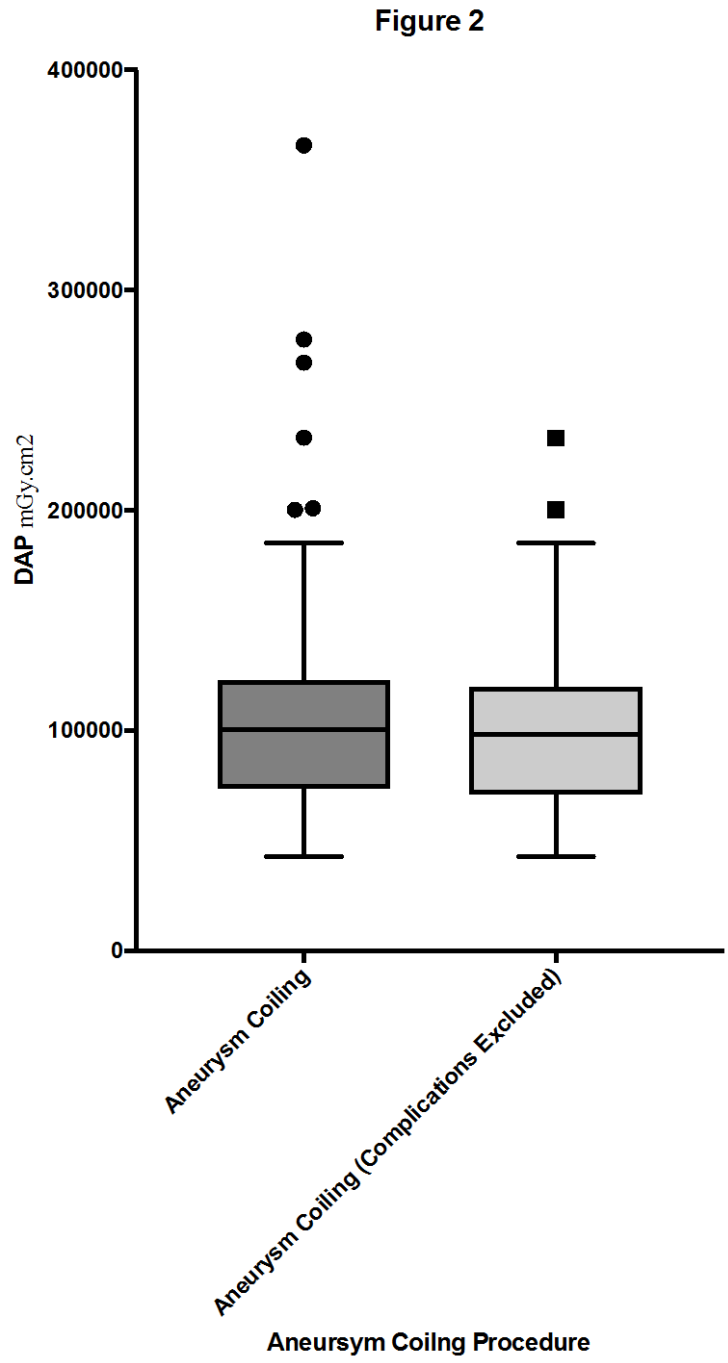
**Table 4.** Excluded variables on dose following stepwise regression analysis

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	3.596E+11	1	3.596E+11	8.934	.004 <sup>b</sup>
	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:** Box and whiskers (Tukey) graph showing median DAP and outliers for all treated aneurysms (including cases with complications) versus DAP for treated aneurysm cases excluding those with intra-operative complications. ( $p = 0.9798$ )

Figure 3

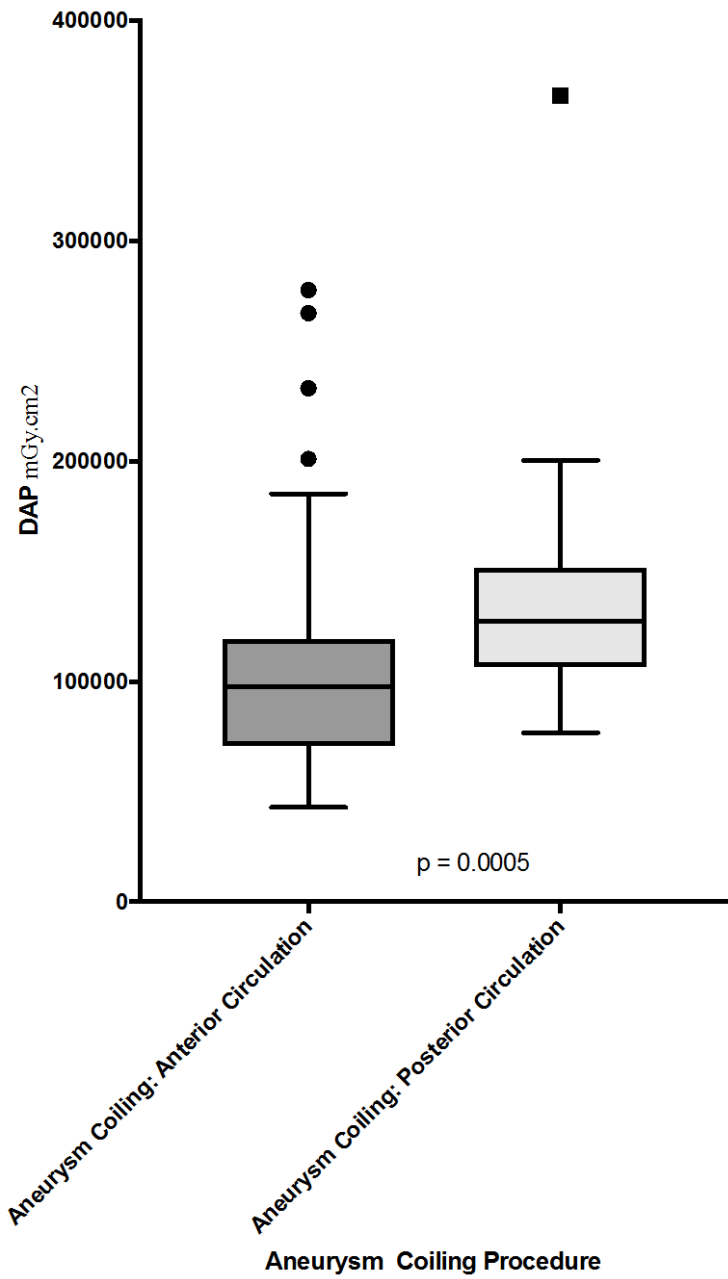


Figure 3: Box and whiskers (Tukey) graph showing median DAP and outliers for treated anterior aneurysms versus posterior aneurysms ( $p = 0.0005$ )

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