Introduction

Interventional neuroradiology is a well-established technique used to treat a variety of conditions of the brain such as aneurysms through complex endovascular approaches which in return has saved the lives of many patients. Endovascular coiling is the current gold standard for treating aneurysms [1.] This intervention uses fluoroscopy for real time monitoring of catheters, wires and device deployment through the blood vessels as well as digital subtraction angiography (DSA) being used for assessing the aneurysm and parent vessels before during and after treatment [2]. This procedure is a minimally invasive treatment and is less traumatic to the patient in comparison to surgery, however it does carry a unique risk over open surgery in that patients and healthcare workers are exposed to ionising radiation during the procedure [3]. Even if the dose used is "as low as reasonably achievable" (ALARA) during the procedure, there is a potential for high radiation exposure as a result of the tendency for extended fluoroscopy screening times, larger numbers of images and lower tube voltages for DSA [4]. As a result, there is a potential stochastic risk to the patient, as well as a risk of tissue effects due to the potential for high skin doses. The magnitude of damage is proportional to dose once the dose exceeds the threshold for the effect. According to the International Commission on Radiological Protection, acute radiation doses distributed to tissues during a procedure or procedures performed within a short period in time, may cause erythema at 2Sv, permanent epilation at 7Sv and delayed skin necrosis at 12Sv [5].

Coiling embolisation was developed over three decades ago and is still considered the gold standard for the treatment of ICA [1]. The aim of endovascular coiling is to isolate the aneurysm from the normal circulation without impeding the parent blood vessel. Multiple coils are packed inside the aneurysm sac to prevent blood flow from entering. However, aneurysm recanalisation is a major drawback of this technique due to coil compaction and occurs in approximately 30% of cases [6]. To prevent this and aid coiling of aneurysms, intracranial balloons and stents were developed. These can provide a more stable aneurysm occlusion compared to standalone coiling by providing a scaffold to protect the parent artery. However, stent treatment requires antiplatelet medication to reduce thrombus formation, which may lead to an increased risk of haemorrhagic events [6]. *Kabbasch et al, (2019)* have noted these types of procedures may be quite complex and may be very time consuming (185 ± 70min), which may in turn give a high radiation dose[7].

In 2011 a new innovative device called the Woven EndoBridge (WEB) was granted the CE mark clearance for commercialisation in the European union. The WEB was introduced for the treatment of a variety of aneurysms, specifically wide necked bifurcation aneurysms [8]. The WEB device is a micro braided mesh constructed from nitinol wires which self-expands once inside the aneurysm's cavity in one deploy. The WEB implant conforms to the aneurysm wall, forming a stable construct across the aneurysm neck which modifies the blood flow at the level of the aneurysm neck [9]. This functions as an intra-saccular flow disruption device, preventing blood from entering the aneurysm and allowing the aneurysm to clot off. Many studies have demonstrated the safety and efficiency of the WEB, with a recent systematic review showing aneurysm occlusion was found in 81% of cases and mortality rates as low as 3% [10]. The WEB device has been shown to be a shorter procedure (109±69 min)[7]. Previous literature has shown that longer fluoroscopy times and procedural complexity have been used as proxies for radiation dose [11].

Monitoring of radiation dose is essential to avoid harm to patients. An estimate of the proximity of an ESD to a threshold would be significant from a radiation safety standpoint. Based off a literature review, Cheung et al (2018) stated that a skin entrance dose exceeds 2Gy in 72% of all neuroendovascular treatments [12]. This dose can result in subacute deterministic effects, as seen in almost 40% of the patients in a study by Peterson et al (2013) receiving >2Gy suffering irreversible tissue damage [13]. In some modern angiographic suites, the c-arm has the capability to measure an air kerma value measured at a specific reference point. This reference point is setup based on an average setup of where the patient's skin would be. As radiation safety remains a fundamental public health issue to both patients and healthcare workers, calculation of the RAK with estimation of the ESD in comparison to the 2Gy threshold is of significant importance.

As per SI. 256 of 2018, all medical radiation exposures must be optimised to meet the ALARA principle [14]. As neuro-intervention is a specialty with the potential to administer high radiation exposures, radiation safety needs to be monitored to see if dose optimisation can be achieved with new techniques. The main purpose of this study is to carry out a KAP/DAP and procedure time audit comparing coiling and the WEB. Limited data is currently available for radiation exposure in endovascular treatment for aneurysms, particularly with respect to the WEB device. A secondary objective of this study is to look at RAK values for high KAP procedures to see if the doses in these procedures exceed 2Gy.

Methods

Study Design

This study was a single centre, non-randomised, retrospective audit that analysed data from the treatment of aneurysms from a picture archiving software (PACS). A study period of 4 years was used (November 2015 - December 2019), as this was the period the WEB device was introduced in this centre. This audit followed the NOCA GDPR guidance for clinical audit and as a result no ethical approval was required [15]. Aneurysm size, treatment type, KAP, fluoroscopy time, procedure time and RAK were the only information needed for this audit. This data was anonymised to safeguard any patient information [15].

Patient Selection

All patients selected to be analysed in this study had to meet the following inclusion criteria: (1) ruptured and unruptured aneurysms status (2) aneurysm size 3 - 11 mm (3) location is within the anterior and posterior circulation of brain (4) successful aneurysm treatments by WEB or coiling techniques (coiling $\pm$ stent or balloon assistance).

Patients who had the following were excluded from the study: (1) pipeline embolisation devices (2) parent artery occlusion (3) dissecting aneurysms (4) treatment for more than 1 aneurysm in the procedure.

This resulted in 47 aneurysms treated with WEB and 104 treated with coiling techniques to have met the inclusion criteria in this study.

Endovascular Procedure

All endovascular techniques were performed through a transfemoral approach and all fluoroscopy, DSA and DYNA was performed on a Siemens Artis DBA biplane c-arm with rotational radiography capability. This allowed for uniformity between KAP and procedure times and how they were captured. The procedures were carried out by two consultant neuroradiologists within this study. The decision to use WEB or coiling was the decision of the neuroradiologists. KAP, fluoroscopy time and procedure time were all recorded on a dose summary report.

Estimation of ESD was performed by summing the RAK in the working projection. The biplane c-arm was able to calculate a RAK at a point 60 cm in the air from the focal spot of the x-ray tube towards the detector for each run.

Data Collection

All data collected in this study was anonymised and I entered onto a password protected excelsheet. Aneurysm size (mm), volume (mm^3), KAP ($\mu Gycm^2$), fluoroscopy time (minutes) and procedure time (minutes) were all recorded in the spreadsheet. Aneurysm size and and volume was estimated using the measurements on the Artis DBA system. KAP was determined by summing the individual radiation contributions on the dose summary report during the relevant runs within the examination i.e. catheterrisation of the internal carotid artery up until the WEB or coiling completion. Fluoroscopy and procedure times were obtained using the timestamps documented in PACS.

RAK in the working projection was recorded for high KAP procedures of each comparator were recorded in excel. Each RAK for each run in the working projection was recorded and summed.

Data analysis

Data analysis was carried out on excel and Stata Release 15.1 (StataCorp, Tx). Data was presented as means for continuous variables. When means are presented, the standard deviation was used to assess sample distribution. Two tailed unpaired t tests were used to compare means, 95% confidence intervals (CI), and p values. A $p < 0.05$ was considered statistically significant.

Aneurysm volume and max diameter were suspected confounders in this study. A linear regression analysis was done on Stata Release 15.1 (StataCorp, Tx) and effect size, confidence intervals and the p-value were also assessed.

RAK were summed together to give an estimate of the total ESD a patient receives at the working projection in the procedure.

Results

(i) Radiation and procedure time audit

Analysis of KAP, fluoroscopy time and procedure time are presented in Table 1. Mean radiation dose for coiling was 6884.1 ± 2774.4 μGym^2 and 5658.7 ± 1602.5 μGym^2 with WEB ($p=0.006$; CI =363-2086 μGym^2). This represented an 18% decrease in mean radiation dose for WEB cases. Mean fluoroscopy times for coiling were 63.5 ± 42.6 minutes and 33.8 ± 28.8 minutes for WEB ($p<0.001$; CI=16-43 minutes). This signified a 50% reduction in fluoroscopy time for WEB cases. Mean procedure times for coiling were 84.2 ± 50.0 minutes and 56.9 ± 30.3 minutes ($p<0.001$; CI=12-43 minutes). This demonstrated a 33% reduction in in procedure time using WEB.

Table 1: Radiation and Procedure time data. (Coiling and WEB values are mean ± Std deviation).

	Coiling	WEB	Difference	Confidence Intervals	P value
KAP (μGym^2)	6884.1 ±2774.4	5658.7 ± 1602.5	1225	363-2086	0.0056
Fluoroscopy time (minutes)	63.5 ± 42.6	33.8 ± 28.8	30	16 - 43	<0.001
Procedure time (minutes)	84.2 ± 50.0	56.9 ± 30.3	27	12 - 43	<0.001
No. of cases	104	47			

(ii) Controlling for aneurysm volume (estimate) and max diameter as confounders

Aneurysm volume and maximum diameter were hypothesised to be confounders in this study. The data analysis showed that neither volume nor diameter seem to be significant predictors of KAP. When controlling for these variables, the KAP for coiling cases is on average 1226 $\mu Gy.cm^2$ higher than for WEB cases (95% CI: 316-2136 $cGy.cm^2$; $p=0.009$); a negligible difference from the unadjusted value.

(iii) RAK evaluation of highest KAP procedures and a case with a complication

RAK values were summed in the working projection. Table 2 gives the breakdown of RAK for high KAP procedure.

Table 2: Table comparing the calculated RAK for the coiling and WEB procedures with the highest KAP recorded in this study.

Procedure	Reference Air Kerma (mGy)		KAP µGym²
	A Plane	B Plane	
WEB (1)	1073.4	734	10710
WEB (2)	696.8	433.5	9567
WEB (3)	886.7	258.9	5596.8
COIL (1)	717.2	565.4	18040
COIL (2)	857.3	848.7	16121.5
COIL (3)	1335.6	1033.5	8807

While RAK is an important estimation of ESD, it does not account for backscatter. As a result, the ESD calculated in this study may be an underestimation due to the fact that no backscatter factor has been considered. *Suzuki et al (2008)* stated that backscatter factors are usually in the range of 1.3 - 1.4 [16]. As a result, an average backscatter factor of 1.35 was applied to the RAK to give a true representation of ESD (Table 3). No cases analysed in this study exceeded the 2Gy threshold dose.

Table 3: Backscatter factor combined to RAK to high KAP procedures.

Procedure	RAK + Backscatter factor (mGy)	
	A Plane	B Plane
WEB (1)	1449.09	990.9
WEB (2)	940.68	585.2
WEB (3)	1197.05	349.515
COIL (1)	968.22	763.29
COIL (2)	1157.4	1145.75
COIL (3)	1803.06	1395.23

Discussion

Since its introduction, the WEB device has proved itself to be an important tool for the treatment of ICAs, particularly wide necked bifurcation aneurysms. The safety and efficacy of the WEB device have been proven in many studies [8-10]. In this present study we show a reduction of KAP (18%), fluoroscopy time (50%) and procedure time (35%) using a WEB device for the treatment of aneurysms compared to conventional coiling, with or without balloon remodelling or stenting. This is the first study to document favourable radiation dose metrics using the WEB device compared to coiling treatment. The reduction in patient radiation dose is important and implements the principle of dose optimisation under S.I. 256 and the European Directive EURATOM 2013/59 [15].

Studies comparing radiation exposure among WEB and coiling of ICA are limited. In contradistinction to our results, Forbrig et al documented no significant difference in mean and median DAP with the WEB device compared to coiling. This may be attributable to a relatively small sample size of the WEB group (n = 21) in this study[17]. Potential differences in neuro-interventionist experience with the WEB device and the exclusion of ruptured aneurysms from this study are additional confounding factors. Forbig et al did however demonstrate a significant reduction in fluoroscopy time with the WEB device when compared to coiling combined with stent placement or balloon remodelling (26 minutes average with the WEB device compared to 94 minutes with combined coiling treatments; $p < 0.001$). There was also a strong trend towards significantly reduced fluoroscopy times with the WEB device compared to coiling alone (26 minutes with the WEB device compared to 49 minutes for coiling alone; $p = 0.06$) [17].

A further novel technique for intracranial aneurysm treatment has been shown to be associated with favourable radiation dose reduction. Colby et al showed significantly reduced radiation dose and procedure times with the use of a pipeline embolisation device, an extrasaccular flow diverter, compared conventional coiling methods [2]. This study compliments our findings and shows that advances in endovascular aneurysm treatment can have additional advantages over coiling methods in ways not originally set out in their development. It is also known that procedure time is inversely related to complication [17] and infection rates [18] and longer fluoroscopy times and procedural complexity can be used as proxies for radiation dose [12]. The use of the WEB with its singular deploy method has distinct advantages over coiling with shorter fluoroscopy and procedural times.

Our analysis showed that neither volume nor diameter seem to be significant predictors of KAP. When controlling for these variables, the KAP for coil is on average 1226µGy.cm^2 higher than for WEB, a negligible difference from the unadjusted value.

Total RAK in the working projection was used to estimate the ESD for high radiation dose procedures. Estimation of radiation dose to the patients' skin is used as a surrogate to assess the possibility of tissue effects due to acute skin exposure to radiation. Based on the results from our study the highest ESD a patient received in a single plane was 1073.4mGy. Analysis was also performed applying a backscatter factor of 1.35 to give a true representation of ESD. By applying the backscatter factor, the ESD values are higher with one value in particular very close to the 2Gy limit. This coiling case had an ESD of 1803.06 mGy in the A plane. This higher patient radiation dose was due to a procedural complication with premature coil detachment and subsequent retrieval. While all cases in this study are below the 2 Gy limit, there remains the potential for high patient radiation doses with neuro-intervention. The significance of dose optimisation cannot be underestimated in this modality. *Li et al (2020)* conducted a study investigating patients who received a cumulative effective dose greater than 100mSv due to fluoroscopy guided interventional procedures [19]. Patients who received these doses had various medical disorders including cancer, chronic disease of the torso, internal bleeding, and cerebrovascular disease [19] · *Peterson et al recorded* a skin entrance dose exceeding 2 Gy in 72% of all endovascular treatments [13]. There remains the need to be acutely aware of patient dose and to improve radiation safety in the neuro-interventional suite to prevent acute deterministic radiation injuries as well as stochastic risk to patients and staff.

While the WEB has the potential to overcome some of the limitations of standard coiling for wide neck bifurcation aneurysms, it is, however, not without its difficulties. Firstly, the WEB device is limited to the manufacture of certain sizes. Not all aneurysms are suitable to conform to the WEB size making it suitable for select aneurysms. Secondly, several authors have shown that adequate patient selection and precise sizing are key issues to achieve treatment success with the WEB device [20]. Inaccurate measurements of the WEB can lead to complications or suboptimal treatment [20]. Finally, WEB baskets are more expensive than coils. *Kabbasch et al (2019)* compared the net material costs for the WEB procedure at €10,506 in comparison to stent assisted coiling at €4410 [7]. This analysis shows that there can be significant cost saving with coiling, however, not all aneurysms are suitable to conventional coiling and we have shown that this comes at a cost of longer procedure and fluoroscopy times.

Limitations

The limitations to this study are mainly related to its non-randomised retrospective design and moderate number of cases in a single study centre. Study design could have been improved by comparing smaller groups of similar aneurysms as well as aneurysm anatomy and location. Matched study design would have strengthened the validity of the results. Although all efforts were made to reduce bias as much as possible, it is possible that that there is a selection bias. Coiling is a well-established method with the WEB device a recent addition. This could potentially allow for the coiling technique being used for an aneurysm that could have been suitable for WEB treatment. However, bias was minimised by ensuring the same angiographic equipment was used throughout this study. As the introduction of the WEB device is relatively recent and reserved for select aneurysms, these factors account for the fewer number of WEB cases compared to coiling cases over the four year period. Later comparisons will be strengthened with greater adoption and adaption of the WEB device.

Estimation of ESD from the summed RAK measurements in the working plane is based on the supposition of a fixed 60 cm focus to skin distance. It is not always possible to get the detector in both planes as close to the anatomy as possible because of the detectors becoming physically in contact with each other and preventing further movement. As a result focus to skin distance can be different for each case. This is a limitation of the RAK value in this study; however, this is something which cannot be avoided due to the need to visualise the aneurysm neck. By including a backscatter factor to the RAK in the working projection, the validity of the results for the ESD has been strengthened. Even with the limitations of this study this is the first time ESD has been reported in a study of the WEB basket and is a starting point in estimating how close the ESD is to the 2Gy limit.

Conclusions

This study demonstrates that the treatment of intracranial aneurysms (size = 3 - 11mm) using WEB devices provides an 18% reduction in KAP, a 50% reduction in fluoroscopy time and a

33% reduction in procedure time compared to conventional coiling techniques. These results add to the growing literature available on the benefits, safety and efficacy of the WEB device. It also demonstrates that there is a potential health benefit to patients as well as operators due to the reduction of KAP noted when using a WEB device. This is an important radiation safety feature of the WEB device.

Conflicts of Interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors

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