



Dose reference levels and clinical determinants in stroke neuroradiology interventions

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Abstract

Objectives To establish dose reference levels (RLs) for stroke interventions while carefully analysing the impact of clinical and technical parameters on patient exposure.

Methods The study retrospectively analysed data from 377 stroke patients prospectively collected between 15 October 2015 and 30 March 2017 at a single, level-3 stroke centre equipped with Philips Allura Clarity systems. Local dose RLs were first derived as the 75th percentile of the dose area product (DAP), cumulative air kerma ($K_{a,r}$), fluoroscopy time (FT) and the number of images (NI). Univariate and multivariate negative binomial regressions were considered for the statistical analysis to investigate the dose variability with clinical and technical parameters such as patient's age and sex, occlusion removal technique, number of passages, single-plane or biplane equipment, etc.

Results Local stroke dose RLs were derived in terms of total DAP (162 Gy cm²), $K_{a,r}$ (854 mGy), FT (42 min) and NI (559). Gender (relative dose multiplier (RDM) 1.31; 95% CI 1.12–1.45), number of passages (RDM 1.22 per passage; 95% CI 1.10–1.22) and procedure success (RDM 0.52, 95% CI 0.55–0.80) proved to be key parameters affecting patient dose. Meanwhile the statistical analysis did not find any difference in relative dose received by patients owing to age, baseline NIHSS score, occlusion removal technique, posterior circulation, support of an anaesthesiologist or use of biplane equipment.

Conclusions Stroke dose RLs introduced in this work promote the optimisation of patient doses. Male gender, number of passages and success of recanalisation are independent key parameters affecting patient dose.

Key Points

- Stroke dose RLs derived in terms of total DAP (162 Gy cm²), $K_{a,r}$ (854 mGy), FT (42 min) and NI (559) will help optimise the radiation safety of patients treated with mechanical thrombectomy.
- Male gender (relative dose multiplier 1.31; 95% CI 1.12–1.45), number of passages (RDM 1.22 per passage; 95% CI 1.10–1.22) and success of recanalisation TICI score > 2b (RDM 0.52, 95% CI 0.55–0.80) are independent key parameters affecting patient dose.
- Stent retriever or aspiration technique showed no significant difference in terms of the dose delivered to the patient; neither technique should be favoured for dosimetric reasons provided that there is no difference regarding clinical outcomes.

Keywords Stroke · Thrombectomy · Radiation protection · Patients · Statistics

Abbreviations

ALARA As low as reasonably achievable
CI Confidence interval

$K_{a,r}$ Cumulative air kerma at interventional reference point
DAP Dose area product
DRLs Diagnostic reference levels
FPCT Flat-panel CT
FT Fluoroscopy time
ICRP International Commission on Radiological Protection
NI Number of images
NIHSS National Institutes of Health Stroke Scale

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PACS	Picture Archiving and Communication System
RDM	Relative dose multiplier
RLs	Reference levels
SILC	Stroke Interventional Laboratory Consensus
TICI	Thrombolysis in cerebral infarction

Introduction

Mechanical thrombectomy is the gold standard for acute ischaemic stroke with large vessel occlusions [1–8]. Recent clinical trials provided compelling evidence that more patients experiencing ischaemic stroke may benefit from endovascular treatment [9–16]. As such, a massive growth in the number of eligible stroke patients and consequently an exponential increase in the number of stroke centres worldwide are expected.

To standardise stroke interventional laboratories and ensure safe, effective and timely stroke care, the Society of Vascular and Interventional Neurology has recently published the Stroke Interventional Laboratory Consensus (SILC) criteria [17]. These criteria use a seven-metrics management approach for the development and standardisation of each stroke interventional laboratory within stroke centres. Among these seven criteria, a safety metric dealing with radiation and procedural safety practices was introduced to discuss general requirements in terms of staff and patient radiation safety as well as ionic contrast safety. This safety metric also discusses the need to monitor and regularly review online dose indicators such as reference air kerma ($K_{a,r}$), dose area product (DAP), fluoroscopy time (FT) and number of acquisition images (NI) to ensure compliance with the ALARA principle. The SILC publication highlighted that average doses for stroke interventions are currently unknown and that reference levels should be specifically defined and used as a guide to good practice.

Indeed, diagnostic reference levels (DRLs) were first introduced in 1996 by the International Commission on Radiological Protection (ICRP) to optimise patients' exposure [18]. Since interventional radiology involves prolonged use of x-rays, the concept of DRLs was later extended to interventional procedures to minimise the risks of deterministic effects which include radiodermatitis or alopecia [19, 20]. In recent years, many studies have shown the feasibility and usefulness of such reference levels as a tool to optimise patients' exposure [21–23]. Additionally, DRLs are regularly updated to include new interventional procedures, account for evolutions in clinical practice as well as in the equipment technology. In fact, an updated guidance on DRLs has been published by ICRP [24] and Etard et al [25] recently documented the results of a multicentre study for the most frequent procedures performed in France. Nonetheless, to date, dose records for stroke neuroradiology interventions

are still scarce [26, 27] and the impact of clinical determinants on patient exposure has not been fully investigated.

Hence, this paper aims to establish dose RLs for stroke neuroradiology interventions while retrospectively investigating prospectively collected clinical determinants which include, in addition to exposure values, information on patients (gender, age, thrombus location, etc.), revascularisation techniques (aspiration versus stent retriever, number of passages, etc.), x-ray equipment (single-plane versus biplane) and treatment outcome (success with thrombolysis in cerebral infarction (TICI) score 2b or 3).

Materials and methods

Thrombectomy procedures

In line with the recommendations of the American Stroke Association and European Stroke Organization, patients received IV thrombolysis (if eligible) and were then transferred to the angiographic suite for urgent thrombectomy [28, 29]. In most cases, thrombectomy was performed under the supervision of an anaesthesiologist with conscious sedation or general anaesthesia. When no anaesthesiologist was present, thrombectomy was performed with local anaesthesia only. Patients underwent thrombectomy with contact aspiration or stent retriever, at the discretion of the operating physician. Solitaire Stent™ (Medtronic, USA) and Trevo Retriever™ (Stryker, USA) devices were most commonly used. In case of carotid occlusion or tandem occlusion, angioplasty of the carotid with or without stenting was performed. Immediately at the end of the mechanical thrombectomy, a systematic flat-panel CT (FPCT) acquisition using the XperCT function (Philips, Netherlands) was performed to depict any haemorrhagic complication or brain parenchymal hyperdense lesions [30].

Study population and prospectively collected data

The study retrospectively analysed data from 377 stroke patients prospectively collected between 15 October 2015 and 30 March 2017. For each patient, the recorded data included age, gender, baseline NIHSS, thrombus location, occlusion removal technique (aspiration and/or stent retriever), number of passes, TICI score, anaesthesia and used x-ray equipment. Patients were excluded from the statistical analysis if no thrombectomy was performed (recanalisation after IV thrombolysis alone; failure to access to the occlusion) ($n = 47$) or if the number of passages was unknown ($n = 10$). One additional patient was excluded from the study as a result of joint treatment of a brain stroke and a lower limb haemorrhage (cf. Fig. 1).

Fig. 1 Flowchart description of patient inclusion/exclusion criteria

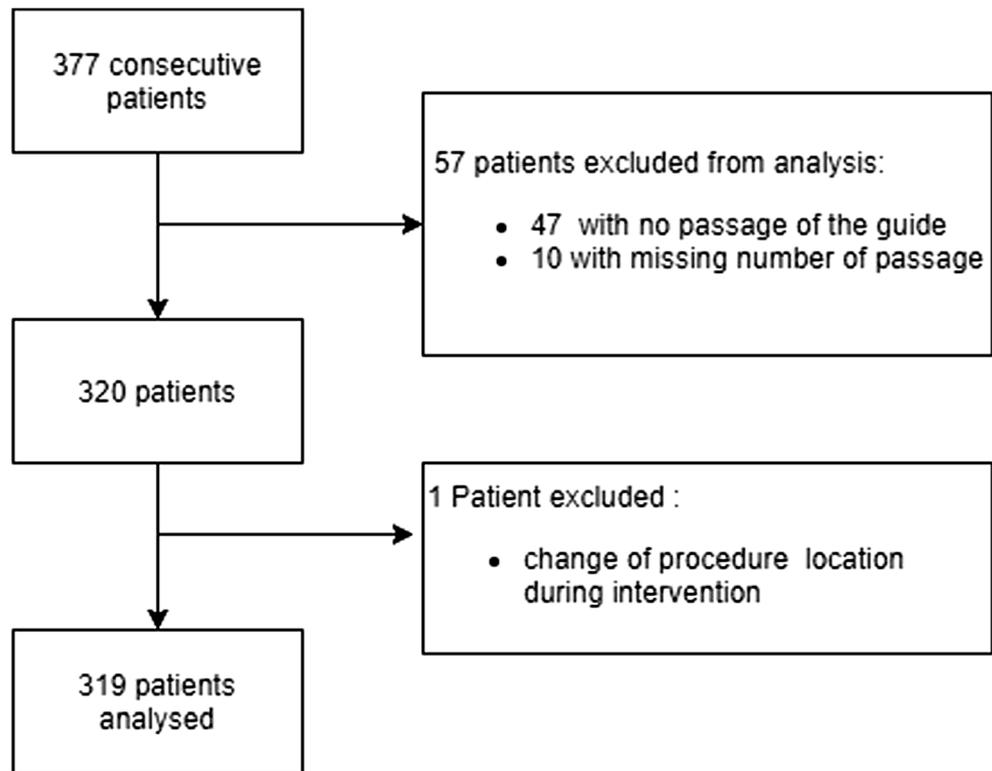


Table 1 summarises the population and procedure information showing that among 319 analysed patients, 46.1% were male and the average age was 71 years (15–103). Most frequent thrombus localisation was M1–M2 segments (66.3%) and mean baseline NIHSS score was 15.28. Stent retriever (SR) was the most frequently used treatment technique (62.3%) with the majority of interventions requiring one passage to remove the thrombus (48.9%). The procedure success rate (TICI score 2b or 3) was 80.5%. The Philips Allura Clarity biplane system was used for 68% of the interventions and 32% were performed using the single-plane system. However, some data were missing for baseline NIHSS (31.7%), thrombus localisation (2.2%), circulation (0.9%), treatment technique (0.9%), TICI score (0.3%) and anaesthesia (1.3%).

X-ray equipment and dose registration

Stroke patients were treated using two different Philips Allura Clarity angiography suites (Philips, Netherlands) with biplane or single-plane x-ray equipment. The biplane system was preferably used to treat stroke patients if available; otherwise the single-plane system was used. Cine acquisitions are typically performed at 2 F/s while fluoroscopy sequences involve 15 F/s. Flat-panel XperCT 3D acquisition protocols were also optimised leading to two standard protocols (operating at 30 F/s, 120 kVp, 240 mAs, 313 images and 60 F/s, 120 kVp, 240 mAs, 626 images). The same acquisition protocols were set on the biplane and on the single-plane

equipment, and both systems were configured identically to guarantee similar performance.

Table 1 Information on demographic/clinical data among the 319 patients recruited in this study

Collected information	Variables	N (% or SD)
Patient-related	Gender (male)	147 (46.1%)
	Age (mean (SD))	71.37 (15.06)
Stroke-related	Thrombus location	M1–M2 207 (66.3%)
		Carotid 47 (15.1%)
		M3–M4 6 (1.9%)
		Tandem 32 (10.3%)
		Other 20 (6.4%)
		Posterior 16 (5.1%)
	Baseline NIHSS (mean (SD))	15.28 (7.29)
Treatment-related	Occlusion removal technique	ASPI 38 (12.0%)
		SR 197 (62.3%)
		SR + ASPI 81 (25.6%)
	Number of passages	1 156 (48.9%)
		2 64 (20.1%)
	≥ 3 99 (31.0%)	
	No anaesthesiologist	58 (18.4%)
Outcome-related	TICI score of 2b or 3–success	256 (80.5%)
Equipment-related	Biplane	217 (68.0%)

SD Standard Deviation

For each procedure, online dose indicators provided by the x-ray equipment include fluoroscopy and acquisition DAPs, $K_{a,r}$ for frontal and lateral tubes (case of biplane), FT and NI that were collected using the local PACS (Carestream). Next, a comprehensive analysis of the dose records was specifically performed for each system and patient, and dose RLs were derived as the 75th percentile of dose distributions. The precision of online dose indicators was checked twice a year following national quality assurance regulations which involve specific test conditions and minimum performance requirements.

Statistical analysis

To study the variability of exposure parameters as a function of the demographic/clinical variables (cf. Table 1), a comprehensive statistical analysis was performed using R version 3.4.0 [31]. As the total (fluoroscopy and acquisition) DAP distribution exhibited left skew and overdispersion, the analysis was performed using a negative binomial model [32]. Univariate negative binomial regressions were performed to select variables for inclusion in a multivariate negative binomial model. A threshold p value set to 0.05 was considered for inclusion in the multivariate analysis. Exponentiated coefficients from the negative binomial models will be reported as relative dose multiplier (RDM) and their 95% confidence intervals (CI) were calculated using the profile likelihood method [32]. P values for multivariate analysis are not reported in order to focus on the effect size and the confidence in the estimated impact of the covariable. Additionally, the number of FPCT procedures performed during one procedure was analysed using a univariate logistic regression while considering the number of FPCT (equal to 1 or larger) as the outcome.

Results

Stroke dose RLs

A total of 319 stroke patients were included in this study. Mean \pm standard deviation, median (1st–3rd quartiles) and range (minimum–maximum) of total DAP, radiography

acquisition and fluoroscopy DAP separately, total $K_{a,r}$, FT and NI are reported in Table 2. Meanwhile, Table 3 documents DAP values as a function of sex, number of passages, occlusion removal technique and TIC1 score.

Statistical analysis of dose determinants

Univariate analysis

Results of the statistical analysis are summarised in Table 4 and Fig. 2.

Male patients had an increase in dose (RDM = 1.31; 95% CI 1.14–1.52, $p = 0.00017$).

Age was not associated with an increase in patient doses.

An overall effect of the location of the thrombus on patient doses was observed ($p = 0.02$). Carotid occlusion was associated with higher dose (RDM = 1.32; 95% CI 1.08–1.64, $p = 0.0077$) compared to M1–M2 occlusions.

Patients treated with stent retriever associated with aspiration received a higher dose (RDM = 1.41; 95% CI 1.09–1.81, $p = 0.0073$) compared to stent retriever alone. However, there was no significant dose difference between stent retriever and aspiration techniques ($p = 0.25$).

Each passage of the thrombectomy device was associated with a relative dose increase of 1.22; 95% CI 1.16–1.28, $p < 0.0001$. Although the large majority of treatments required only one (48.9% of the cases) or two (20.1%) passages of the thrombectomy device to remove the thrombus, the remaining 31% of the procedures involved 1.66–4.91 times (corresponding to three and eight passages, respectively) more exposure of the patient compared to one-passage treatments.

Procedures with successful reperfusion (TIC1 2b or 3) had significantly lower doses with a DAP lower by 0.52 (95% CI 0.44–0.61, $p < 0.0001$) compared to non-successful procedures (TIC1 score 0–2a).

No significant difference was observed according to the baseline NIHSS score, location of the occlusion in the anterior or posterior circulation, nor to the intervention of an anaesthesiologist during the procedure.

No significant dose difference was observed following the use of the single-plane or the biplane Philips Allura Clarity system.

Table 2 Summary of exposure parameters for the 319 stroke patients included in this study

$N = 319$	Mean \pm SD	Median (range)	1st quartile	RL—3rd quartile
Total DAP (Gy cm ²)	123 \pm 95	94 (16–533)	62	162
Fluoroscopy DAP (Gy cm ²)	64 \pm 61	46 (9–416)	27	80
Radiography DAP (Gy cm ²)	57 \pm 42	44 (76–280)	29	72
Total $K_{a,r}$ (mGy)	704 \pm 589	524 (66–4518)	328	854
FT (min)	35 \pm 27	26 (7–226)	17	42
NI	434 \pm 357	315 (52–3090)	203	559

SD Standard Deviation

Table 3 Mean ± standard deviation, median (1st–3rd quartiles) and range (minimum–maximum) of total DAP for the 319 stroke patients included in this study as a function of sex, thrombus location, number of passages, occlusion removal technique and TIC1 score

DAP (Gy cm ²)		Mean ± SD	Median (range)	1st–3rd quartile	RL—3rd quartile
Sex	Female	107 ± 77	84 (16–449)	59	127
	Male	141 ± 109	113 (23–533)	64	176
Thrombus location	M1–M2	114 ± 90	84 (16–524)	56	142
	Carotid	130 ± 93	108 (34–421)	63	160
	Tandem	144 ± 87	123 (27–445)	75	189
Number of passages	1	92 ± 79	66 (16–504)	50	100
	2	122 ± 71	102 (28–302)	72	158
	≥ 3	171 ± 109	144 (29–533)	100	217
Technique	Stent retriever	113 ± 84	88 (16–533)	58	153
	Aspiration	104 ± 105	66 (29–504)	52	109
TICI score	< 2b	203 ± 121	173 (55–532)	118	248
	2b or 3	104 ± 76	77 (16–485)	56	125

SD Standard Deviation

Multivariate analysis

Results of the multivariate analysis are presented in Table 5 and Fig. 3.

In multivariate analysis, male gender was still associated with a relative increase of dose (adjusted relative dose multiplier for male vs. female, 1.28; 95% CI 1.12–1.45). The success of the procedure was also a determinant of the DAP with an adjusted relative dose multiplier of 0.67; 95% CI 0.55–0.80.

Each additional passage of the thrombectomy device was still associated with an increase of DAP (adjusted relative dose increase of 1.15; 95% CI 1.10–1.22), independently of the success of the procedure.

Thrombus location and treatment technique were no longer associated with dose modification in the multivariate analysis results.

Flat-panel CT contribution to patient dose

As previously mentioned, a flat-panel CT acquisition (Philips XperCT) is typically performed at the end of each thrombectomy to detect brain parenchymal hyperdense lesions. Although the majority of those patients (69.7%) received only one FPCT exam, few patients received 0 (8.1%), 2 (15%) or at least 3 (7.2%) FPCT acquisitions. The average DAP of each 3D acquisition was 24 Gy cm², hence representing a contribution to the total patient DAP of

Table 4 Summary of the univariate statistical analysis results

Collected info	Variables	Relative dose multiplier	95% CI	p value	Overall p value
Patient-related	Gender: male vs. female	1.31	1.14–1.52	0.00017	–
	Age	1	1.00–1.01	0.8	–
Stroke-related	Location: carotid vs M1–M2	1.32	1.08–1.64	0.0077	0.02
	Location: tandem vs M1–M2	1.24	0.98–1.59	0.084	
	Location: M3–M4 vs M1–M2	0.79	0.48–1.40	0.38	
	Location: other vs M1–M2	1.22	0.92–1.67	0.19	
	Posterior vs. anterior circulation	1.14	0.83–1.62	0.43	–
Treatment-related	Baseline NIHSS	1.01	0.99–1.02	0.39	–
	SR + ASPI vs. ASPI	1.41	1.09–1.81	0.0073	0.01
	SR vs. ASPI	1.14	0.90–1.42	0.25	
	Number of passages	1.22	1.16–1.28	< 0.0001	–
Outcome-related	No anaesthesiologist	0.97	0.80–1.17	0.72	–
	TICI score 2b or 3—success	0.52	0.44–0.61	< 0.0001	–
Equipment-related	Single-plane vs. biplane	0.92	0.79–1.08	0.31	–

Bold entries indicate relative dose multipliers with significant p values

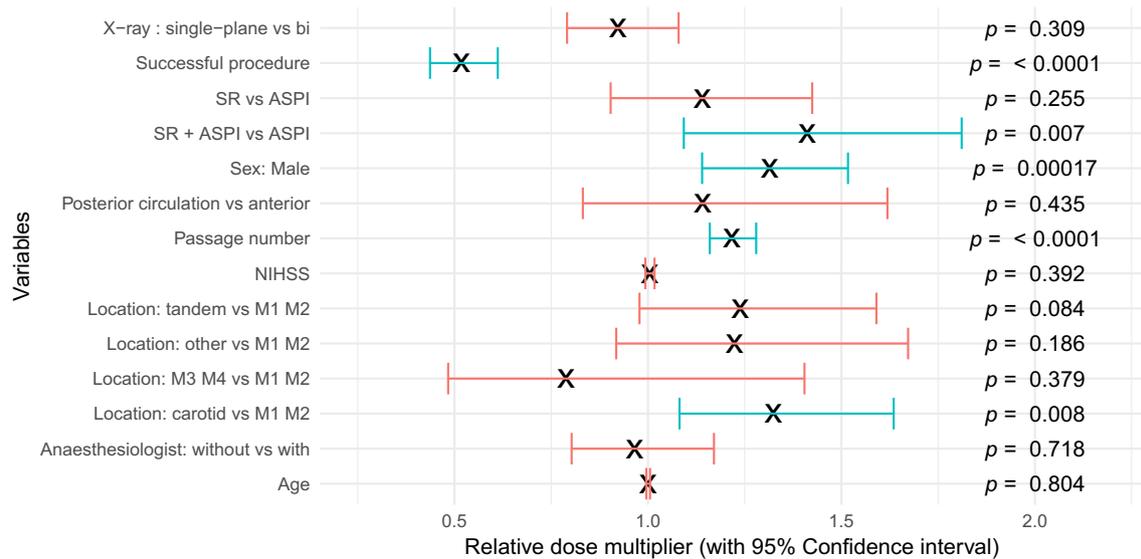


Fig. 2 Relative dose modification and confidence interval for clinical and technical variables considered in the univariate statistical analysis

18.2% (range 2.4–76.8%); the largest FPCT contributions were registered in the case of very fast procedures with FT typically less than 10 min.

The statistical analysis highlighted an inverse association between the number of XperCT acquisitions and the success rate of the procedure (odds ratio = 0.39, 95% CI 0.21–0.73, $p = 0.0029$). This was the only variable showing a statistically significant association with the number of FPCTs.

Discussion

This study introduced dose RLs for mechanical thrombectomy interventions with data collected from one comprehensive stroke centre. The large number of patients included in this study (319 compared against the typical 30 patients used to define local dose RLs) and the wide demographic and clinical characteristics of the study population

prove the robustness of the suggested local dose RLs as a function of clinical determinants.

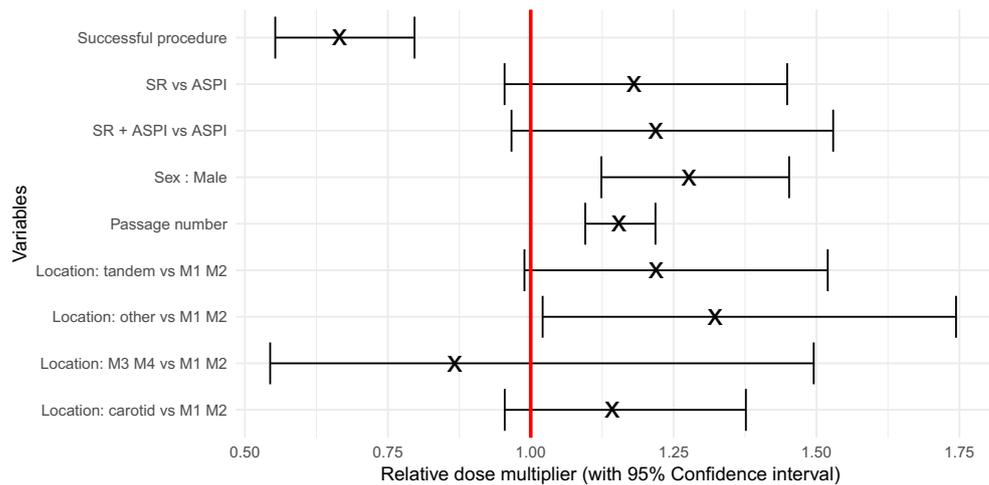
Stroke dose RLs provided in Table 2 are found to be generally lower than literature data [22, 25] for arteriovenous malformations (285–550 Gy cm² or 3230–6000 mGy) and aneurysm embolisations (190–360 Gy cm² or 2770–4750 mGy) proving that mechanical thrombectomy does not necessarily induce larger radiation risks for patients and consequently for operators. Additionally, data in Tables 2 and 3 were compared against average dose records for aspiration (20.5 min, 472 Gy cm²) and stent removal techniques (12.42 min, 327 Gy cm²) reported by Brown et al [26] for a limited subset of patients. Although average FT values documented here (29 min for both SR and aspiration) are larger than those of Brown et al [25], DAP values in Tables 2 and 3 are much lower, indicating good local practice and radiation optimisation thanks to Clarity IQ technology (Philips, Netherlands). Additionally, Brown et al [26]

Table 5 Summary of the multivariate statistical analysis results

Collected info	Variables	Adjusted relative dose multiplier	95% CI
Patient-related	Gender: male vs. female	1.28	1.12–1.45
Stroke-related	Location: carotid vs M1–M2	1.14	0.95–1.38
	Location: tandem vs M1–M2	1.22	0.99–1.52
	Location: M3–M4 vs M1–M2	0.87	0.54–1.50
	Location: other vs M1–M2	1.32	1.02–1.74
	Baseline NIHSS		
Treatment-related	SR + ASPI vs. ASPI	1.22	0.97–1.53
	SR vs. ASPI	1.18	0.95–1.45
	Number of passages	1.15	1.10–1.22
Outcome-related	TICI score 2B or 3—success	0.67	0.55–0.80

Bold entries means relative dose multipliers with significant p values

Fig. 3 Relative dose modification and confidence interval for clinical and technical variables considered in the multivariate statistical analysis



found no statistically significant difference in DAP between aspiration and stent removal ($p = 0.137$); this was also confirmed by the present study. Finally, Hassan and Amelot [27] reported dose RLs for 73 stroke patients showing lower average DAP (110 Gy cm^2) and FT (30 min) than those presented in Table 2, implying further potential optimisation. However, the comparison is not straightforward since clinical determinants, which largely affect patient exposure (cf. Table 3), were not reported by Hassan and Amelot [27].

Male patients received higher doses than female patients, although gender was not suspected to be a factor influencing the radiation dose in such stroke neurointerventions. However, the patient's morphology was not considered (since the study focused on neurointerventions) in the multivariate analysis and this might be a confounding factor considering that men are generally heavier than women.

No correlation between age and the delivered dose was observed. This is surprising given that older patients usually present tortuous anatomy and difficulty regarding catheterisation and access to the occlusion site owing to vascular ageing [33–35]. It was hence expected that older patients would receive higher doses compared to younger patients given that procedures usually last longer.

No significant difference in dose between stent retriever and aspiration techniques was found. This result suggests that procedural doses are similar regardless of the occlusion removal technique. Hence, stent retrieval or aspiration technique should not be favoured for dosimetric considerations provided that there is no difference regarding clinical outcomes [36].

While the number of attempts required to remove the thrombus is known to reflect the complexity of the procedure, this parameter also proved to be the most important factor affecting patient doses. Recanalisation success rate was about 80.5% and some occlusions might be difficult to recanalise despite several

attempts [4]. In such specific cases, patients' and consequently operators' exposure to ionising radiation should be considered.

This study did not identify a significant increase of patient doses with the use of the biplane equipment, although slightly higher doses were registered on this system compared to the single-plane equipment. Additionally, with similar success rates, one can elude that optimally used single-plane equipment is appropriate for stroke thrombectomy.

Finally, the analysis showed that for few patients (8.1% of the sample), no FPCT acquisitions were performed; this is probably an oversight and a deviation from the standard protocol. For some patients (15%), an extra FPCT was performed before starting the procedure to check the absence of intracranial haemorrhage (i.e. haemorrhagic transformation); this is typically the case with “drip-and-ship” patients who received IV thrombolysis in a distant centre and observed a modification of their clinical examination. For a limited number of patients (7.2%), several FPCTs were sequentially performed because of patient motion and movement artefact. Nonetheless, the overall limited contribution of FPCT acquisitions to the total interventional DAP supports the systematic use of FPCT acquisition to depict any blood–brain barrier rupture or intracranial haemorrhage due to arterial perforation after thrombectomy directly in the vascular room [30], hence avoiding patient transfer to CT equipment.

Study limitations

This single-site study presents several limitations due to the retrospective analysis of the data and the study population sample.

First, the suggested stroke dose RLs might not be generally applicable because of the impact of confounding variables among the stroke centres such as setup, configuration and protocol optimisation differences of x-ray equipment, local practice and experience, etc. A more extensive use of the

methods presented here at multiple sites with agreed upon fluoroscopy system optimisation would be needed for more universally accepted dose RLs. Nonetheless, Table 3 provides DAP values as a function of sex, number of passages, occlusion removal technique and TICI score (the most relevant parameters) which could be used for refined comparisons.

While information on sex, age, number of passages and used x-ray equipment was available for all 319 patients, some data were missing for baseline NIHSS (31.7%) which stands against any overinterpretation of the negative result of the statistical tests.

The impact of patient morphology on the dose was not considered in this study since the core of the procedure is located at the level of the head where morphology should not be affected by gender. However, collecting a patient's height and weight data, which might have produced a better predictor of patient dose than gender, proved necessary even in neurointerventions. Additionally, given the limited dosimetric information available on the PACS, it was not possible to investigate the contribution of fluoroscopy while moving the catheter across abdominal and thoracic regions where the patient's anatomy/thickness may induce larger doses in men compared to women.

Additionally, this study did not compare to the exposure of a FPCT vs. a standard CT head acquisition considering that a sound and robust conversion methodology is not available.

Finally, statistical tests did not identify a significant impact of posterior circulation, thrombus location or occlusion removal technique; this could be due to unbalanced groups in the study sample.

Stroke dose RLs introduced in this work are useful to promote the optimisation of patient doses. Male gender ($\times 1.31$), each passage ($\times 1.22$ per passage) and success of recanalisation ($\times 0.52$) are independent key parameters affecting patient dose.

Ultimately, since the performance of health systems is increasingly associated with treatment quality and outcome measures, it is our belief that patient dose can be considered as a key quality indicator reflecting the clinical complexity of the procedure and the risk to the patient.

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Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Pr Laurent Spelle.

Conflict of interest The authors of this manuscript declare relationships with the following companies: Philips, Medtronic, Stryker, MicroVenton, Balt.

Statistics and biometry One of the authors has significant statistical expertise.

Informed consent As a follow-up evaluation on stroke patients, informed consent was not required.

Ethical approval As a follow-up evaluation, the study did not involve any change in the standard procedure and did not require the identification of individuals.

Methodology

- retrospective
- observational
- performed at one institution

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