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Effect of aneurysm size on procedure-related rupture in patients with subarachnoid hemorrhage treated with coil occlusion☆

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ABSTRACT

Objective: Procedure-related rupture is one of the most feared complications in treating patients with cerebral aneurysm. The primary aim of this study was to estimate the effect of aneurysm size on procedure-related rupture. We also estimated its effect on peri-procedural thromboembolic events.

Methods: This observational study was conducted using routinely-collected health data on patients admitted for subarachnoid hemorrhage and treated with aneurysm coil occlusion in the CHU de Québec — Enfant-Jésus hospital from January 1st, 2000 until sample size was reached. Patients were identified from the Discharge Abstract Database using the Canadian Classification of Health codes. Assessment of complications was blind to aneurysm size. Logistic regression models were performed to test associations between aneurysm size and procedure-related rupture or peri-procedural thromboembolic events, and between both procedure-related rupture and thromboembolic events and patients' outcomes.

Results: This study included 532 aneurysms treated with coil occlusion in 505 patients. Procedure-related rupture occurred in 34 patients (6.7%) and thromboembolic events in 53 (10.5%) patients. Aneurysms of 2 to 3 mm inclusively were not more significantly associated with procedure-related rupture or thromboembolic events than those larger than 3 mm (OR 1.02, 95% CI: 0.9–1.16, $p = 0.78$ and OR 1.06, 95% CI: 0.96–1.17, $p = 0.3$, respectively). However, procedure-related rupture had a significant effect on patient mortality (OR 3.86, 95% CI: 1.42–10.53, $p < 0.01$).

Conclusions: Very small aneurysm size should not preclude aneurysm coil occlusion. Every measure should be taken to prevent procedure-related rupture as it is strongly associated with higher mortality.

1. Introduction

Procedure-related rupture is one of the most feared complications of aneurysm treatment [1–6]. Small aneurysm size (3 mm or less) has been associated with a higher risk of procedural-rupture during coil occlusion compared to larger aneurysm size in three studies, published between 2001 and 2011, and including either exclusively [7] or mostly [6,8] ruptured aneurysms of any size. To our knowledge, a single study reported similar risks of endovascular treatment in small or larger aneurysms [9], but only unruptured aneurysms were included. Many other case series have reported various estimates of procedural rupture during coil occlusion of very small aneurysms only. Those studies included either exclusively ruptured aneurysms [10–16], or a mix of ruptured and unruptured ones [17–24]. Their results have been pooled in a meta-analysis [25] which has found that procedural rupture rate reported during endovascular coil occlusion of very small aneurysms published after 2010 was lower than those reported in studies published before 2010. The reported estimates must be interpreted cautiously due to the substantial heterogeneity of the studies included in the meta-analysis. While this suggests that the complications rate of endovascular

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coil occlusion of very small aneurysms may currently be lower than it was in the past [15,25–27], it does not show that aneurysm size does not influence the risk of procedural rupture anymore.

We performed an observational study, using routinely collected heath data, on patients with ruptured aneurysm treated with coil occlusion. The aims of our study were to estimate the effect of aneurysm size on procedure-related ruptures and thromboembolic events; and the effect of those events on patient mortality and discharge destination.

2. Method

The institutional review board of the institution gave ethics approval for the study and waived the need for patient consent. We reported our findings in accordance with The Reporting of studies Conducted using Observational Routinely collected Data (RECORD) Statement [28].

2.1. Study population

This study was conducted on all consecutive patients admitted for subarachnoid hemorrhage and treated with aneurysm coil occlusion at Enfant-Jésus Hospital, between January 1st, 2000 until sample size was reached. Enfant-Jésus Hospital is a tertiary care university hospital that provides all neurosurgical services for Quebec City and for the eastern part of the province of Quebec, Canada. Patients were identified from the Discharge Abstract Database (DAD) of the CHU de Québec Data Warehouse. DAD is an administrative dataset mandated by regulatory bodies that contains diagnostic, procedural, demographic, and administrative information for every hospitalization in Canada. The diagnosis and procedure codes used in the DAD are captured according to the Canadian Classification of Health codes. A model including procedure code for aneurysm endovascular treatment (occlusion of intracranial vessels; ICD code = 1JW51) and diagnosis code for subarachnoid hemorrhage (intracranial hemorrhage code = I61) had already been validated to predict that a patient had a primary subarachnoid hemorrhage according to health administrative data [29].

The patients included in our cohort were identified from the DAD using these codes, with an additional specification for coiling (occlusion of intracranial vessels with use of detachable coils; ICD code = 1JW51.GP-GE). The electronic health record of the patients in the DAD-generated database was then screened for inclusion/exclusion criteria. Patients were included if they had confirmed acute subarachnoid hemorrhage and at least one aneurysm treated with selective coil occlusion in the Enfant-Jésus Hospital during the same hospitalization. Diagnosis of subarachnoid hemorrhage was confirmed by a review of the health record to find either presence of blood in the subarachnoid space, according to the pre-treatment CT scan report, or xanthochromia in the cerebrospinal fluid (CSF) confirmed as positive by laboratory analysis. If the patient was transferred from another hospital and the scan report from this hospital was unavailable, and no new scan had been performed pre-treatment in the CHU de Québec, the CT scan results recorded in the neurosurgery consultation report were used. We excluded patients with aneurysms related to arteriovenous malformations and aneurysms treated with occlusion of the parent vessel.

2.2. Outcome definition

The primary outcome, procedure-related rupture, was defined as (a) contrast extravasation during angiography recorded on the procedure report, (b) new or worsening subarachnoid bleeding, (c) presence of contrast within the subarachnoid space, or (d) new hematoma recorded on the post-treatment day-1 CT-scan report.

Secondary outcomes were other procedural complications defined as (a) presence of an intra-arterial clot needing fibrinolysis treatment and/or new ischemia on post-treatment day-1 CT-scan (thromboembolic events), (b) coil migration requiring retrieval technique or (c) failure to deliver any coil into the aneurysm (failure of treatment). The patient's status (alive or dead) when hospitalization ended (from DAD) was recorded to assess mortality rate. The discharge destination from our hospital was also recorded (home, rehabilitation center, long-term care facility, or transfer to another hospital). Discharge to a long-term care facility or rehabilitation center was considered as a surrogate for poorer outcome; while home discharge was considered as a surrogate for a better outcome. We considered transfer to another hospital as poorer outcome, as the patient usually stay longer at the hospital.

2.3. Data recording

This study was based on electronical health data records from the CHU de Québec Data Warehouse. We used only data in emergency department records, in patient clinical records and radiological records, from hospital admission to discharge, of patients admitted for acute subarachnoid hemorrhage and for whom aneurysm coil occlusion was performed in Enfant-Jésus hospital during this same hospitalization. A coding system was used to classify all outcomes and variables. The senior author trained the first reviewer (a neurosurgery resident) in data recording using a structured collection form so she could confirm/clarify the coding and find the exact location in the patient's health record in which each variable was recorded. Then the first reviewer trained the second reviewer (a clinical intensive care unit nurse), using five patient health records. After the training, all demographic, radiological and medical data on the first 50 included patients were recorded independently by the two reviewers. Reviewers reviewed all conflicting data and reached consensus adjusting the collection form when needed. Then only one reviewer continued collecting data.

2.4. Blinding

To assure that data recording on complications was blinded for aneurysm size, we copied all aneurysm coil occlusion procedure reports and a research assistant blocked out any mention of aneurysm size before the report copy was reviewed for complications. In the same manner, the reviewer collecting demographic and clinical data was blinded for aneurysm size. Even if the aneurysm size and the intraprocedural rupture clearly defined and obtained from medical record was less prone to interpretation, reports interpretation could not have been excluded. In this situation, blinding insured that if any misinterpretation occurred, it was not biased and remained systematic for all aneurysm sizes.

2.5. Statistics

Sample size was determined by setting a difference of 1 mm in aneurysm size as the threshold for showing any effect on procedure-related rupture using the Z test approximation for logistic regression estimated with GPower 3.1.7. [30]. A pilot study conducted earlier on small ruptured aneurysms treated with coil occlusion in the CHU de Québec — Enfant-Jésus Hospital found a procedural rupture rate of 4.5%. A median aneurysm size of 6 mm with an interquartile range (IQR) of 4.5 mm to 8.7 mm was used as the size distribution (based on a subgroup of patients with ruptured aneurysms previously treated in the CHU de Québec — Enfant-Jésus Hospital [31]). Considering confounding factors to have an effect of 10%, a sample size of 524 was required to obtain a power of 80%.

Baseline data were reported as descriptive analyses with continuous variables (mean ± standard deviation, median and IQR) and categorical variables (frequency and percentage). Statistical analyses were performed using bivariate and multivariate logistic regression models in order to establish the association between aneurysm size and procedural complications, considering age, initial GCS score, patient's wait from arrival to treatment, hypertension, and tobacco use as potential confounding factors. We also analyzed the effect of the patient's

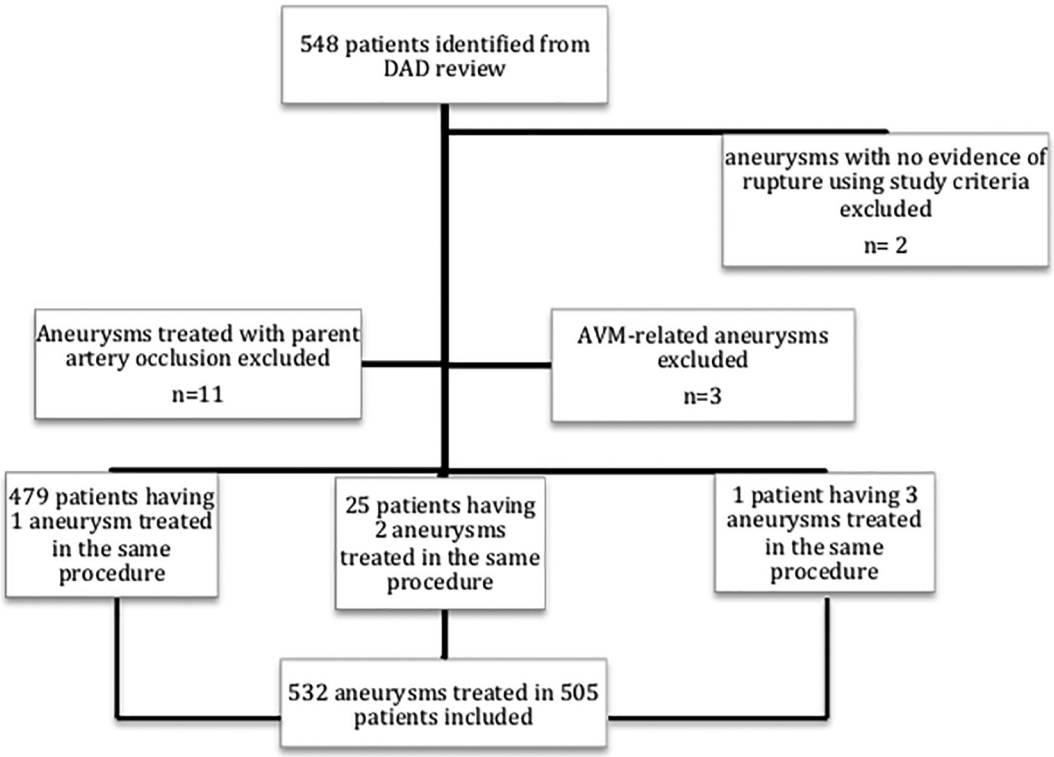

Fig. 1. Study flow chart.

treatment year on procedure-related rupture and aneurysm size, using year of treatment as a continuous variable and with dichotomization (until 2006 compared to after 2006). The Lemeshow goodness-of-fit test was used to evaluate the models. A receiver operating characteristic (ROC) curve was also obtained to assess if aneurysm size could be used to predict the risk of procedure-related rupture based on our analyses. In these analyses, each aneurysm was analyzed separately. If multiple aneurysms were treated during the same procedure, and when the data could not tell us which aneurysm was responsible for the complication recorded, the complication was recorded for both aneurysms. The effects of procedural complications on mortality and morbidity were analyzed using the Chi-squared test for categorical factors and the F-test or Mann-Whitney-*U* tests when appropriate. Statistical analyses were performed using SAS Statistical Software v.9.4 (SAS Institute, Cary, NC, USA) with a two-sided significance level set at $p < 0.05$.

3. Results

Fig. 1 shows study flow chart. To obtain our sample size, 548 patient health records were screened from the database generated from code searching in DAD. We found 532 aneurysm cases consecutively treated with coil occlusion on 505 patients that corresponded to our inclusion criteria. Multiple aneurysm treatments were performed during the same procedure in 26 patients (53 aneurysms).

All patients were treated after general anesthesia and administration of systemic heparin. Table 1 shows baseline characteristics of patients and aneurysms/procedural data. Aneurysm size ranged from 2 mm to 26 mm with a median of 5.8 mm, and a lower quartile between 2 mm to 2.5 mm.

Table 2 shows procedure-related complications with occurrence of procedure-related rupture in 34 procedures (6.4%). Thromboembolic events occurred in 53 procedures (10%), including 8.5% with new ischemia in the same area as the aneurysm being treated according to the CT-scan on post-treatment day-1. Seven (1.3%) aneurysms were referred for surgical clipping following failure of endovascular

Table 1
Baseline data (N = 505 patients; N = 532 aneurysms).

Age (mean)	55.7
Sex, n (%)	
Female	328 (64.9)
Male	177 (35.1)
Tobacco use, N (%)	
Active	160 (34.2)
Unknown	121 (25.9)
Blood pressure, N (%)	
Hypertension	151 (32.3)
Unknown	10 (2.1)
Initial Glasgow Coma Scale score, N (%)	
14–15	366 (72.4)
9–13	64 (12.7)
3–8	70 (13.7)
Unknown	5 (1.1)
External ventricular drain, N (%)	200 (39.6)
Type of aneurysm treated, N (%)	
Total aneurysms	532 (100)
ACom	228 (42.8)
Pericallosal	25 (4.7)
Carotid bifurcation, choroïdal and para-ophthalmic	41 (7.7)
PCom	111 (20.9)
MCA	38 (7.1)
Basilar trunk and PICA	35 (6.6)
Basilar tip and PCA	54 (10.2)
Aneurysm size, mm, median (IQR; range)	5.8 (2.5–8; 2–26)
Aneurysm neck size, mm, median (IQR; range)	3 (2–3; 1–9)
Coil occlusion procedures, N (%)	
Total coil occlusion procedures	532 (100)
Standard coiling	420 (79.0)
Balloon assisted coiling	110 (20.0)
Coiling and stent	2 (0.4)

A comm, anterior communicating artery; IQR, interquartile range; MCA, middle cerebral artery; N, number; PCA, posterior cerebral artery; P comm, posterior communicating artery; PICA, posterior inferior cerebellar artery.

Table 2
Procedural complications and failures of treatment (N = 532 procedures).

Complication/failure	N (%)
Procedure-related rupture	34 (6.4)
Intra-parenchymal bleeding progression	22 (4.1)
Thromboembolic event	53 (10.0)
Intra-arterial clot formation*	8 (1.5)
New ischemia on CT scan†	45 (8.5)
New ischemia in a different vascular area‡	7 (1.3)
Arterial dissection	1 (0.2)
Coil migration	3 (0.6)
Failure rate	9 (1.7)

CT, computerized tomography; N, number.
* Requiring fibrinolysis treatment.
† In the same vascular area as the treated aneurysm.
‡ In a different vascular area than the treated aneurysm.

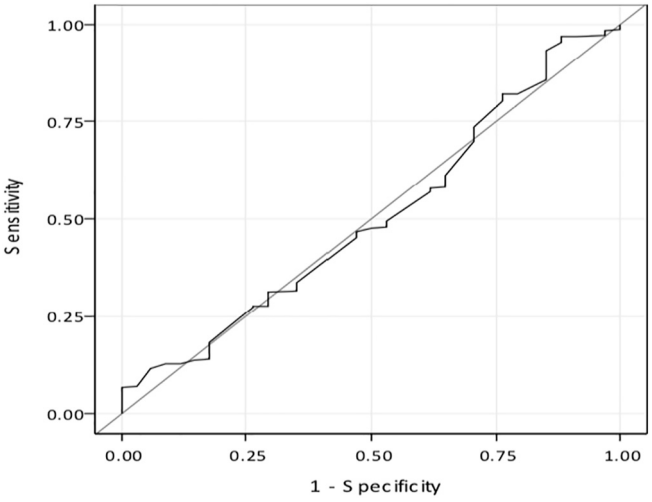

Fig. 2. ROC curve of aneurysm size for procedure-related rupture.

treatment.

The ROC curve showed that aneurysm size had very low predictive power for procedure-related rupture (Fig. 2). This prevented us from identifying a precise cut-off point for aneurysm size. Moreover, procedural complications analyses were done using multiple size cut-off (< 2 mm vs ≥ 2 mm, < 3 mm vs ≥ 3 mm, < 4 mm vs ≥ 4 mm, < 5 mm vs ≥ 5 mm, < 6 mm vs ≥ 6 mm) and no specific size cut-off showed effect on complication occurrence.

Therefore, for publication purpose, we analyzed the effect of aneurysm size on procedural complications using an arbitrary size cut-off point of 3 mm, which is the size used in most studies involving very small intra-cranial aneurysms. Our analyzes revealed no significant association between aneurysm size and occurrence of our identified complications, including procedure-related rupture. Table 3 shows the effect of aneurysm size (3 mm or smaller compared to bigger than 3 mm) on complications rate. Aneurysm size had no significant effect on procedure-related rupture (OR = 1.02; 95% CI = 0.9–1.16; p = 0.8), after adjustment for age, GCS score on arrival, hypertension, tobacco use and the patient's wait from arrival to treatment.

Treatment year showed no effect on association between procedure-related rupture and aneurysm size (data not shown). There was no effect either when the progression of pre-existing intraparenchymal bleeding (which can be due to heparin treatment alone) was added to the model. Moreover, aneurysm size had no effect on thromboembolic events (OR = 1.06; 95% CI = 0.96–1.17; p value = 0.3) after adjustment for age, GCS score on arrival, hypertension, tobacco use and wait for treatment.

Forty-two patients died during their hospitalization. Occurrence of procedure-related rupture and thromboembolic events both had a significant effect on patient mortality (Table 4). Among patients who survived, four were transferred to a long-term care facility, 99 were transferred to a rehabilitation center and 64 were transferred to another hospital. None of the four patients transferred to a long-term care facility had procedure-related rupture, thromboembolic event or other procedural complications.

Fifty-six percent of patients with procedure-related rupture who survived had a poor outcome. Patients with procedure-related rupture were significantly more likely to be transferred to a rehabilitation center than to be discharged home (OR 2.52; 95% CI = 1.13–5.63; p = 0.02), considering transfer to another hospital as a poor outcome. However, this was not significant after adjustment for age, EVD placement and GCS score on arrival (OR = 2.39; 95% CI = 0.91–6.29; p = 0.07). None of the patients with thromboembolic events (including outside the vascular area of the treated aneurysm) had higher morbidity, with or without adjustment for age, EVD placement and GCS score on arrival.

4. Discussion

In this study of 532 aneurysms treated with coiling, very small aneurysms (from 2 to 3 mm inclusively) were not more significantly associated with procedure-related rupture than larger aneurysms (> 3 mm). However, higher mortality rates were associated with procedure-related rupture. The occurrence of procedure-related rupture significantly reduced the likelihood of being discharged home in our cohort, but this effect was not significant after adjustment for confounding factors.

4.1. Effect of small aneurysm size on the risk of procedure-related rupture

Nguyen et al. [7] studied the effect of aneurysm size on procedure-related rupture in a cohort of 682 intracranial aneurysms treated with coil occlusion and found that very small aneurysms (3 mm or smaller) were five times more likely to result in procedure-related rupture than larger aneurysms. The evolution of coil and catheter technology may

Table 3
Effect of aneurysm size 2–3 mm compared to aneurysm size > 3 mm on procedural complications.*

All aneurysms (N = 532)	Size 2–3 mm (N = 66)	Size > 3 mm (N = 444)	Size N/A (N = 22)	Odd ratio† (95% CI)	*P* value
Procedure-related rupture N = 34 (6.4%)	2 (3%)	32 (7%)	0 (0%)	1.02 (0.90–1.16)	0.77
Thromboembolic event N = 52 (9.7%)	3 (4.5%)	48 (10.8%)	1 (4.5%)	1.06 (0.96–1.17)	0.27
Procedure-related rupture and thromboembolic event N = 86 (16.2%)	5 (7.6)	80 (18%)	1 (4.5%)	1.03 (0.94–1.12)	0.49

CI, confidence interval; N, number; N/A, not available.
* Results of analyses using best-case scenario (no complications) for the 11 patients with no CT scan performed on arrival.
† Adjusted for age, GCS score on arrival, hypertension, tobacco use, patient's wait from arrival to treatment.

Table 4
Effect of procedure-related rupture and thromboembolic event on patient mortality.

	Mortality n (%)	Odds ratio* (95% CI)	*P* value
Procedure-related rupture (N = 34)	7 (20.6)	3.86 (1.42–10.53)	< 0.01
Thromboembolic event (N = 53)	8 (15.1)	3.20 (1.27–8.03)	< 0.01

CI, confidence interval; n, number.
* Adjusted for GCS score on arrival, EVD and age.

have reduced the risk of procedure-related rupture over time, particularly in the subset of small aneurysms. In our study, the rate of procedure-related rupture (6.4%) and its association with aneurysm size were not significantly influenced by the year of treatment. A recent meta-analysis of endovascular treatments of very small aneurysms including 22 studies from 2006 to 2015, found that procedure-related rupture occurred in 9% (95% CI, 6%–12%) of ruptured small aneurysms [25]. However, when authors analyzed outcomes between studies included in a prior meta-analysis [26] and those included in this meta-analysis, procedure-related rupture rates were found to be lower in more recent studies (3% compared to 7%, $p = 0.07$).

4.2. Morbidity and mortality associated with procedure-related rupture

Nguyen et al. [7] and Sluzewski et al. [6] have suggested that, in the event of a procedure-related rupture, clinical outcomes tend to reflect one of two extremes: patients either do well or die. This may be related to the speed with which control of hemostasis and intracranial pressure can be regained. The significant effect of procedure-related rupture on mortality in our study is similar to that reported elsewhere in the literature [6,7,25]. Other studies have also shown a significantly higher mortality rate with no significant effect on morbidity [6]. However, outcomes were measured using the Glasgow Outcome Scale and the modified Rankin Scale, scales whose principal aim is to estimate outcome in prospective trials but not validated for use in retrospective studies [32]. This may have resulted in deduction of outcomes, which are more likely to be biased than accurate. While the discharge destination used in our study is a very short-term outcome and is still an imprecise surrogate for absolute outcome at discharge, it is at least an objective measurement and can help dichotomize short-term outcomes into those that are relatively better (i.e. home discharge) and relatively worse (e.g. discharge to a long-term care facility). Our analysis showed that procedure-related rupture significantly reduced the likelihood of being discharged home, but this effect was not significant after adjustment for age, GCS score and EVD (a potential marker of either high-grade subarachnoid hemorrhage and/or hydrocephalus), while the risk of committing a type 1 error in accepting this hypothesis remains low ($p = 0.07$).

4.3. Study strengths and limitations

To reduce the risk of biases, the investigators were blinded to aneurysm size and we used objective definitions and measurement criteria for clinical and radiological data as well as for outcomes. The high inter-observer agreement between reviewers on the first 100 patient charts confirmed the reliability of our measurements for assessing our outcomes. However, due to the retrospective design of our study some morphological data on the aneurysms other than their size were missing in our analysis, and these could also have influenced peri-operative risk. Moreover, the absence of a precisely defined method for measuring aneurysm size in routine radiological reports compared to the precise prospective measurements recorded for research purposes may have introduced errors in measuring aneurysm size. However, these errors should be systematic ones, i.e. they will affect both the group with and without procedure-related rupture in the same way. The retrospective design of our study also excluded more sensitive information that could have been collected in a prospective trial through standardized physical and radiological examinations (such as diffusion weighted magnetic resonance imaging). This missing information may have resulted in an underestimation of thromboembolic events in this study. In our opinion, however, the definition of our primary endpoint (procedure-related rupture) is sensitive enough to consider that its validity is very close to the validity of the same endpoint measured prospectively, and even if we cannot verify this hypothesis and exclude all risk of measurement errors in our results, there is again no reason to doubt that these errors would be systematic for aneurysms of every size. Finally, considering the good statistical power of our study and the precision of our measure (95% CI: 0.899–1.155) around the OR estimate (1.0), the probability for a type II error is very low.

As far as external validity is concerned, the size distribution of our aneurysms was similar to that in other studies on ruptured aneurysms [33] and the contrast extravasation rate was also comparable to that in similar studies (Nguyen et al. [7] 3.1% vs 2.4% in our study). On the other hand, our aneurysm size distribution (2–26 mm) does not allow us to exclude a possible effect of aneurysm sizes smaller than 2 mm on complication rates, including that of procedure-related rupture. Since blister aneurysms are not usually treated using endovascular coil occlusion, it is an expected result that none of the aneurysms included in our study had the classical characteristics of a blister aneurysm, and that our results do not apply to this particular subgroup. Since we stopped our analysis after the sample size was reached (latest patients were treated in 2013), we did not include patients treated with the latest technologies but this should not have biased our results toward underestimation of the primary endpoint. However, even if small case series have evaluated the safety of new endovascular technologies and seem to show that new coils and micro-catheters technology are at low risk of procedural rupture for small aneurysms (≤ 3.5 mm) [34,35], we cannot exclude that those technologies may increase the risk of complications during endovascular treatment of very small aneurysms. Therefore, our results cannot be generalized to small aneurysms treated with those devices.

5. Conclusions

According to our results, very small aneurysm sizes ranging from 2 to 3 mm inclusively were not more significantly associated with procedure-related rupture than aneurysms larger than 3 mm and should not preclude aneurysm coil occlusion. On the other hand, procedure-related rupture should be avoided by all means as it is significantly related to higher mortality and could also reduce the likelihood of being discharged home after a subarachnoid hemorrhage. Consequently, other trials should aim to identify modifiable risk factors, such as those technically-related, that could influence procedural strategies or eventually guide new technologies development and further decrease the risk of this complication in the future.

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Declaration of competing interest

The authors declare that there is no conflict of interest.

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