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The impact of selection bias in the treatment for ruptured anterior communicating artery aneurysms: different results or different patients?

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ABSTRACT

Background: Anterior communicating artery is one of the most frequent locations for the development of intracranial aneurysm. The availability and advances of different treatments modalities allows for case-specific selection, but potentially impacts our ability to assess equipoise among them.
Objective: Investigate and compare clinical and morphological variables among surgical and endovascular treatment groups with ruptured anterior communicating artery aneurysms.
Methods: Data from patients from a single university hospital treated for ruptured anterior communicating aneurysms after multidisciplinary discussion in a period from January 2009 to January 2020 were retrospectively reviewed. Demographics, clinical status, aneurysm morphologic features and in-hospital complications were registered for each treatment (endovascular coiling vs. microsurgical clipping). Clinical assessment was made from outpatient evaluation at 1-year follow-up.
Results: A total of 119 patients was obtained adding surgical ($n = 80$) and endovascular ($n = 39$) treatment groups. No significant changes between groups were detected regarding gender, age of treatment or other risk factors. Global complication rate ($p = 0.335$, $p = 0.225$, $p = 0.428$) and clinical outcome ($p = 0.802$) was similar among both groups. Univariate and multivariate analysis revealed statistically significant differences between endovascular and surgical treatment groups regarding dome orientation ($p = 0.011$), aneurysm height ($p < 0.001$) and maximum diameter ($p < 0.001$), aspect-ratio ($p < 0.001$), dome-to-neck ratio ($p < 0.001$) and dome diameter ($p = 0.014$).
Conclusions: Despite similar clinical outcomes and rate of complications, morphological differences highlight the presence of a selection bias and high heterogeneity, which hampers inferential analysis when comparing both techniques.

1. Introduction

Cerebral aneurysms are a frequent diagnosis with a worldwide estimated prevalence of up to 3 %.[1,2] The anterior communicating artery (AComA) complex is recognized not only one of the most frequent sites for aneurysm formation[3] but also one with the highest estimated rupture rate.[4] Furthermore, AComA region presents a significant challenge regardless of the treatment, due to frequent anatomical variations that may shift the efficacy of either endovascular or surgical treatment.[5]

Although recent studies have been focusing the management and treatment orientation for intracranial aneurysms, there is still no consensus regarding a *one-fits all* technique. The advent of endovascular procedures and the technical evolution of the devices brought a global shift towards a less-invasive interventions.[6–8] Despite this, microsurgical treatment remains as a cornerstone in aneurysm exclusion, as it provides a high exclusion rate in most cases. Moreover, recent prospective data showing long-term results on both treatment options document such higher total exclusion rates in surgical treatment group and a high cross-over from endovascular group, underlining a potential source for bias.[9]

Our objective was therefore to analyze clinical and morphological data on both proposed and effective treatment groups, hypothesizing a

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significant difference and possible bias effect between groups that may hamper direct comparison.

2. Methods

2.1. Background and study design

A retrospective study was conducted after Ethics Committee approval of full protocol. All patients proposed and treated for ruptured anterior communicating aneurysms in a single University Hospital from January 2009 to January 2020 were eligible. Treatment groups were neurosurgical (microsurgical clipping) or endovascular (single coiling). Exclusion criteria included patients younger than 16 years old, patients with multiple aneurysms with persistent doubt about the rupture site and lack of quality/absence of available imaging studies.

In our center, subarachnoid hemorrhage in patients with clinical and/or imagological suspicion undergo vascular study with angio-CT scan with 3D reconstructions (3D-CTA) and, in selected cases, confirmation or complementary study with digital subtraction angiography (DSA). In the confirmation of an aneurysmatic lesion, primary orientation is responsibility of the Neurosurgeon in collaboration with the Neuroradiologist (which performs the endovascular treatment) to determine the best option for treatment.

Demographic and individual clinical variables were assessed retrospectively from clinical records and previous known history and included gender, age of treatment, history of arterial hypertension or smoking, family history, presence of multiple aneurysms, clinical status on admission and classification (Hunt and Hess, World Federation of Neurosurgical Societies/WFNS and modified Fischer/mFischer grades). Data regarding the hospitalization included time until treatment (TUT), time on intensive-care unit (TICU) and presence of complications such as late hydrocephalus, presence of ischemic lesions and arterial vasospasm. Morphologic features included dome projection, neck-diameter, aneurysm height, Aspect ratio, size ratio and dome-to-neck ratio.

2.2. Definition of aneurysm dome projection

Aneurysm projection was determined considering the orientation of the dome in the sagittal plane of 3D-CTA images taking as references a virtual parallel line to the skull base and a second perpendicular line intersecting the anterior communicating artery complex. The positional relation between the axis of the aneurysm and the lines determined the projection in eight different positions, as proposed by Ganaha et al[10] (Fig. 1).

2.3. Morphologic features of the aneurysm

Morphologic measurements were performed by a single observer on retrospective review of the pre-treatment 3D-CTA.

Aneurysm neck was measured as the diameter of the origin of the lesion on the tangential plane of the vessel. Aneurysm height was obtained from the distance from the neck mid-point to the dome. In case this was not the largest axis of the aneurysm, a measurement of the maximum diameter of the aneurysm was also registered.

Vessel size associated with the aneurysm was considered regarding the position to the aneurysm: proximal (mother-vessel) or distal (daughter-vessel). Size ratio was calculated according to the relation between the aneurysm height and vessel size.

2.4. Intrahospital events

Event-specific intrahospital complications were registered for each

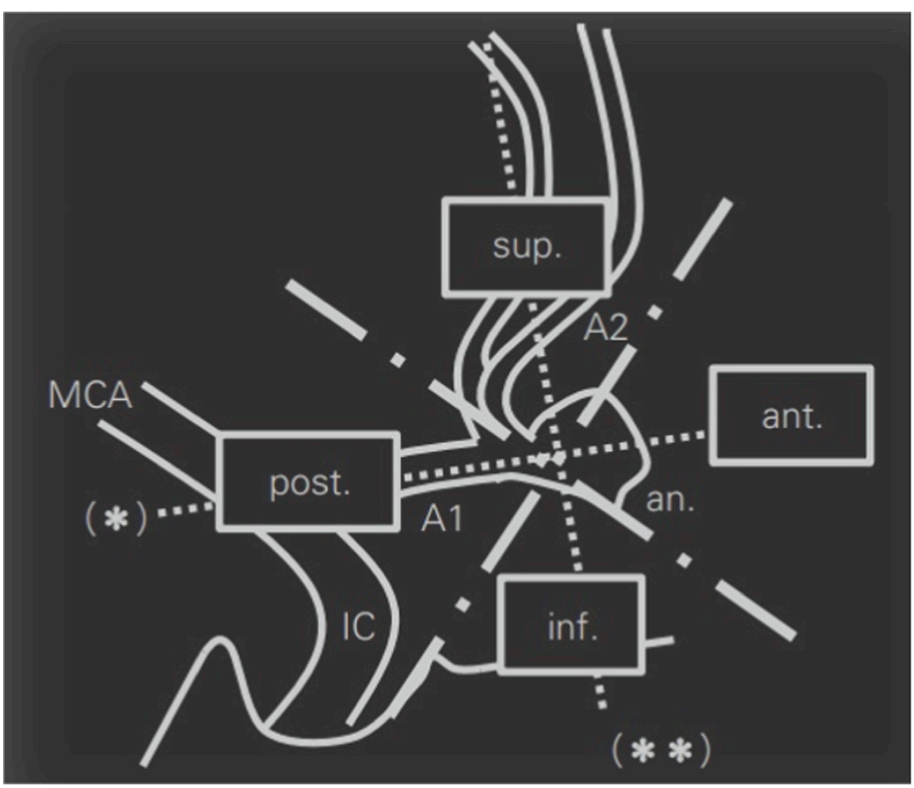

Fig. 1. Orientation of the aneurysm dome. Eight different projections were considered (anteroinferior, anterior, anterosuperior, superior, posterosuperior, posterior, posteroinferior, inferior).
(*) Line parallel to the anterior skull-base passing through the AComA.
(**) Perpendicular line to the (*) axis.
Adapted from Ganaha et al.[10]

treatment (endovascular coiling vs. microsurgical clipping): ischemic lesions (defined as *de novo* matching CT-scan hypodense areas on postoperative imaging control and at least one subsequent imaging study), arterial vasospasm (according to sonographic criteria on consecutive ultrasounds in the early postoperative period) and late hydrocephalus (ventricular dilation deemed indicated to ventriculoperitoneal shunting).

2.5. Functional status

Functional assessment consisted of outpatient evaluation by the assisting clinician at 1-year follow-up and classified according to modified Rankin scale (mRs).

2.6. Data treatment and statistical analysis

Normal distribution was assessed using histogram graphics. Categorical variables were presented as frequencies (percentages) and continuous variables as means ± standard deviation. Aneurysm dome-neck orientation was dichotomized in anterior (which included anterosuperior and anteroinferior) or non-anterior (superior, posterosuperior, posterior, posteroinferior and inferior) according to its projection (Fig. 1) and all morphological, demographic and clinical variables were compared between proposed treatment and actual treatment groups. Univariate analysis was performed using independent-sample *t*-test for continuous variables comparison, Chi–Square test for categorical variables and non-parametric tests (Mann–Whitney *U*-Test and Kruskal–Wallis) whenever normal distribution was not verified. Multivariate analysis was performed afterwards for significant variables assessment and control for confounders. Variables with a p value < 0.05 were deemed significant. Statistical analysis was performed with IBM SPSS version 28.0 (IBM SPSS, Armonk, NY, US).

3. Results

A total of 119 patients were obtained and eligible for inclusion. Mean age was 54.1 ± 13.29 (range 17.4–80.6) and 67 patients (56.3 %) were female. 69 patients (58.0 %) presented with a mFischer scale of 4. Total complication rate was 46.2 % for arterial vasospasm, 41.2 % for ischemic lesions, 17.6 % for late hydrocephalus and the mortality rate was 7.6 %. TICU was 20.0 ± 14.7 days. 67.0 % of the patients presented with a mRs of either 0 or 1 at one-year assessment.

AComA aneurysms showed an anterior projection in 62.2 % of the cases. The mean neck diameter and height were 3.31 ± 1.08 mm and 5.45 ± 2.64 mm, respectively. Proposed treatment consisted in microsurgical clipping in 41 (34.5 %) patients and endovascular coiling in 74 (62.2 %) patients. 4 (3.4 %) patients underwent digital subtraction angiography and subsequent surgical treatment, but there was insufficient data to infer about the first intention of treatment. Actual treatment consisted of microsurgical clipping in 80 (67.2 %) patients whereas the remaining 39 (32.8 %) underwent endovascular coiling. The global cross-over rate from endovascular to surgical treatment was 47.3 % ($n = 35$). No patients crossed to the endovascular side. Regarding clinical, demographic and event-related variables, time until treatment (TUT) showed higher values in the microsurgical clipping group (71 ± 95.7 vs. 45.2 ± 46.1, $p = 0.019$). Further patient variables and comparison variables are characterized in Table 1.

Univariate analysis of the intent to treat analysis showed significant differences among treatment groups (microsurgical vs. endovascular) regarding the height of the aneurysm (4.67 ± 2.07 vs. 5.84 ± 2.85; $p = 0.029$), aspect-ratio (1.36 ± 0.55 vs. 1.89 ± 0.76; $p < 0.001$) and dome-to-neck ratio (1.24 ± 0.39 vs. 1.62 ± 0.75; $p < 0.001$). Effective treatment comparison further showed statistically significant difference across all variables except for neck-diameter ($p = 0.409$), as shown below in Table 2. Assessment of dome orientation showed a tendency for anterior AComA aneurysms towards endovascular intent-to-treat group and a significant difference in effective treatment comparison ($p = 0.126$ and $p = 0.006$, respectively). Further details regarding the specific orientation are shown in Table 3 and Fig. 2.

Multivariate analysis revealed a strong association after adjustment for possible confounders between effective treatment and aneurysm height, aspect ratio, dome diameter, dome-to-neck ratio, maximum diameter, size ratio and dome orientation (Table 4).

4. Discussion

Our study aimed to highlight the presence of selection bias in both treatment groups. In our center, patients with ruptured AComA aneurysms showed up having similar age and gender distribution, risk factors and clinical presentation among groups. Despite this, a clear-cut contrast is noticed when comparing morphology among treatment groups, particularly in the effective treatment analysis.

The significant difference in time until treatment (TUT) among groups of actual treatment is in line with our expectations and easily

Table 1
Univariate analysis regarding comparison between surgical and endovascular proposed and effective treatment groups. Independent sample *T*-test was performed for continuous variables, whereas Chi–Square test was conducted for categorical variable.

Characteristics	Proposed treatment			Actual treatment		
	Microsurgical clipping	Endovascular coiling	*p* value	Microsurgical clipping	Endovascular coiling	*p* value
Gender (male/female)	17/24	33/41	0.746	34/46	18/21	0.706
Age of treatment, mean ± SD	53.2 ± 13.6	54.6 ± 13.1	0.670	53.3 ± 13.0	55.6 ± 13.9	0.538
Hypertension, n (%)	22 (53.7 %)	33 (44.6 %)	0.351	39 (48.8 %)	18 (46.2 %)	0.790
Dyslipidemia, n (%)	13 (32.5 %)	27 (36.5 %)	0.606	23 (28.7 %)	18 (46.2 %)	0.061
Diabetes mellitus, n (%)	3 (7.3 %)	8 (10.8 %)	0.542	9 (11.3 %)	2 (5.1 %)	0.279
Smoking, n (%)	17 (42.5 %)	29 (42.6 %)	0.988	28 (38.4 %)	20 (51.3 %)	0.188
Multiple aneurysms, n (%)	4 (9.8 %)	12 (16.2 %)	0.338	9 (11.3 %)	9 (23.1 %)	0.091
GCS, median [IQR]	14 [13–15]	14 [13–15]	0.923[a]	14 [13–15]	14 [11–15]	0.947[a]
Hunt&Hess, median [IQR]	2 [2–3]	2 [2–3]	0.862[a]	2 [2–3]	2 [2–3]	0.764[a]
WFNS grade, median [IQR]	2 [1–3.5]	2 [1–3.25]	0.970[a]	2 [1–3.75]	2 [1–4]	0.950[a]
mFischer, median [IQR]	3 [2–4]	4 [3–4]	0.119[a]	4 [2–4]	4 [3–4]	0.381[a]
mRs pre, median [IQR]	0 [0-0]	0 [0-0]	0.470[a]	0 [0-0]	0 [0-0]	0.722[a]
mRs post, median [IQR]	1 [1–2]	1 [0–2]	0.844[a]	1 [1–2]	1 [1–2]	0.802[a]
TUT, mean ± SD	72.8 ± 95.3	58.4 ± 78.6	0.238	71 ± 95.7	45.2 ± 46.1	**0.019**
TICU mean ± SD	20.8 ± 15.2	18.9 ± 14.1	0.451	20.3 ± 13.6	19.5 ± 16.9	0.434
Late hydrocephalus, n (%)	8 (19.5 %)	11 (14.9 %)	0.520	16 (20.0 %)	5 (12.8 %)	0.335
Ischemic lesions, n (%)	21 (51.2 %)	27 (36.5 %)	0.125	36 (45.0 %)	13 (33.3 %)	0.225
Arterial vasospasm, n (%)	16 (39.0 %)	35 (47.3 %)	0.392	39 (48.8 %)	16 (41.0 %)	0.428

SD – standard deviation; IQR – interquartile range.
[a] Non-parametric test was performed (Kruskal–Wallis test) due no non-normal distribution.

Table 2
Univariate analysis showing morphological comparison between surgical and endovascular proposed and effective treatment groups.

Characteristics	Proposed treatment			Actual treatment		
	Microsurgical clipping	Endovascular coiling	*p* value	Microsurgical clipping	Endovascular coiling	*p* value
Neck-diameter (mean ± SD)	3.51 ± 1.10	3.19 ± 1.05	0.133	3.37 ± 1.06	3.19 ± 1.12	0.409
Height (mean ± SD)	4.67 ± 2.07	5.84 ± 2.85	**0.029**	4.63 ± 1.99	6.95 ± 3.02	<**0.001**
Aspect ratio (mean ± SD)	1.36 ± 0.55	1.89 ± 0.76	<**0.001**	1.43 ± 0.61	2.24 ± 0.71	<**0.001**
Dome diameter (mean ± SD)	4.42 ± 2.13	5.01 ± 2.58	0.234	4.30 ± 1.92	5.66 ± 2.93	**0.012**
Dome-to-neck ratio (mean ± SD)	1.24 ± 0.39	1.62 ± 0.75	<**0.001**	1.30 ± 0.48	1.83 ± 0.81	<**0.001**
Maximum diameter (mean ± SD)	5.76 ± 2.36	6.85 ± 3.35	0.078	5.55 ± 2.20	8.10 ± 3.68	<**0.001**
Size ratio (mean ± SD)	3.29 ± 1.35	4.00 ± 2.14	0.076	3.17 ± 1.34	4.78 ± 2.33	<**0.001**

Table 3
Dome orientation comparison between surgical and endovascular proposed and effective treatment groups.

Dome orientation	Proposed treatment			Actual treatment		
	Microsurgical clipping	Endovascular coiling	*p* value	Microsurgical clipping	Endovascular coiling	*p* value
Anterior (1)	6 (15.4 %)	16 (22.2 %)	–	13 (17.3 %)	9 (23.1 %)	–
Anterosuperior (2)	6 (15.4 %)	21 (29.2 %)	-	17 (22.7 %)	10 (25.6 %)	-
Anteroinferior (3)	11 (28.2 %)	14 (19.4 %)	-	13 (17.3 %)	13 (33.3 %)	-
Superior (4)	6 (15.4 %)	7 (9.7 %)	-	13 (17.3 %)	2 (5.1 %)	-
Posterosuperior (5)	2 (5.1 %)	2 (2.8 %)	-	3 (4.0 %)	1 (2.6 %)	-
Posterior (6)	–	–	-	–	–	-
Posteroinferior (7)	–	–	-	–	–	-
Inferior (8)	8 (20.5 %)	12 (16.7 %)	-	16 (21.3 %)	4 (10.3 %)	-
Anterior (1,2,3)	23 (59.0 %)	51 (70.8 %)		43 (57.3 %)	32 (82.1 %)	
Non-anterior (4–8)	16 (41.0 %)	21 (29.2 %)	0.126	32 (42.7 %)	7 (17.9 %)	**0.006**

explained with the high cross-over rate and most patients in the "endovascular coiling" proposed treatment arm. Besides, changes in the paradigm of treatment in our center also limit our ability to infer any conclusion, both on a quantitative and comparative basis.

The results from International Subarachnoid Aneurysm Trial (ISAT) fueled a major shift in the paradigm and a growing trend in the endovascular era.[11,12] American Heart Association guidelines for the management of aneurysmal subarachnoid hemorrhage (aSAH) currently recommends endovascular approach as a first-line treatment option for aneurysms amenable for both types of treatment.[13] However, even disregarding the meaning of "technical feasibility", a multitude of other factors are to consider when evaluating a patient for a treatment modality. Individual factors, clinical presentation and even local availability or team expertise of such treatment modalities are major aspects to include in the individual decision-making process.[14,15]

Our cross-over rate was 47.3 %, which is a high value even considering global rates of large prospective data.[9] Although reasons were not always objectively identified, they ranged from lack of stabilization of coiling, wide-neck aneurysms or bad aspect ratio. Differences in the morphology and the high cross-over rate in the coiling group underscore once more the effect and extent of selection bias, as shown by large follow-up cohort studies: major data from an unselected patient cohort such as the Barrow Ruptured Aneurysm Trial (BRAT) document global cross-over rates of 36 % and stress again the selection criticism around the ISAT, where the inclusion criteria would only allow patients unambiguously amenable to endovascular treatment.[9,11]

Global measurements and comparison of the morphological parameters are in line with previous evidence. Darkwah et al reported smaller aneurysms and lower dome-to-neck ratios being more prone to microsurgical clipping.[16] Classically, smaller and wide-neck aneurysms are recognized as less suitable for endovascular treatment.[14,15,17,18] It is interesting to highlight that aneurysm neck diameter is the only morphological parameter not showing difference among effective treatment groups, showing that despite frequent and shallow inferences regarding these lesions, there is much more to account as the real challenges in the treatment of AComA region aneurysms.

Anterior-projection aneurysms constituted most treated lesions with almost two thirds of our total population. This goes in line with previous reports which state a possible higher risk for rupture of these lesion types.[4,19] Data comparing both techniques and dome orientation is however scarce in ruptured aneurysms, even though it is being described more and more as a factor to consider when deciding elective treatment.[20] Considering the local anatomy and oversimplifying, aneurysms with an anterior projection tend to be in general technically less demanding, as shown in our results by both the high cross-over rate and the type of aneurysms crossing to the surgical side.

Regardless, aspect ratio seems to be one of the strongest predictors, with higher ratios correlating strongly to endovascular treatment group.[16] Size ratio also related to the risk of rupture[19,21] and classical factors such as the size of the aneurysm may have limited isolated correlation with the risk of rupture, as some series report almost a third of the ruptured AComA aneurysm as very small ($\leq$ 3 mm).[21]

Global rate of complications and mortality, as well as clinical outcome at 1-year follow-up also did not show any significant differences, which goes in line with previous studies.[15,18] Safety of endovascular treatment is highly regarded and there are numerous papers describing better clinical outcomes in the endovascular side.[22] Nevertheless, as previously stated and in the absence of a controlled environment, patient selection is crucial and individual series with direct comparison should be taken with a pinch of salt.

It is important however to mention that we addressed the single-coiling technique in the endovascular treatment group. Stent-assisted coiling, as well as major developments and surging of new technologies such as flow-diverters and endovascular devices may shift the trend for high-complexity aneurysms and recent data suggest they might have superior safety to microsurgical clipping, although only unruptured aneurysms are analyzed and, once more, selection of the patients is paramount.[23]

There are however some limitations to our study. Despite solid clinical and morphological data from a tertiary hospital, this is still a retrospective analysis, which limits any causal inference. Scarcity of some clinical records, particularly in older patients, is also to note, as it would provide more indication on whether endovascular treatment was not successful. This was also a significant limitation in the decision-making of comparing our clinical results, as neuropsychological evaluations would provide more useful information in these specific patients

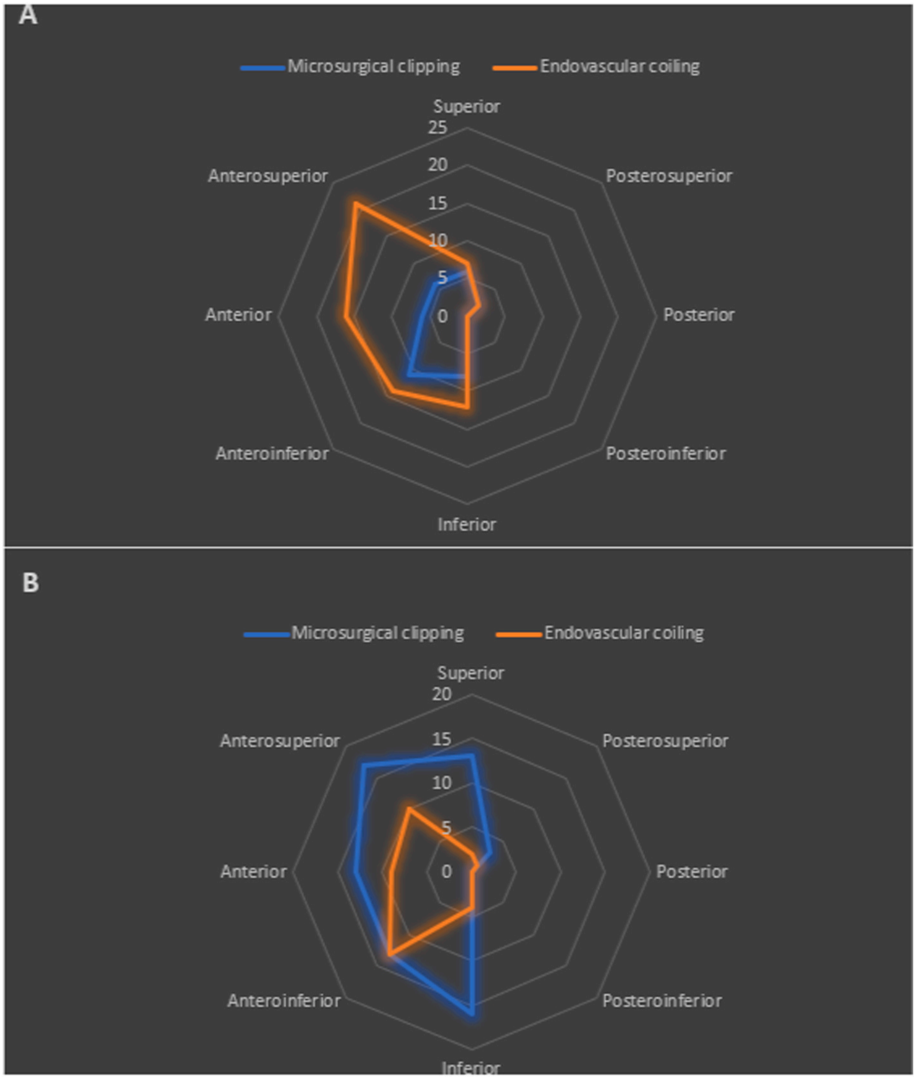

Fig. 2. Graphic representation of dome orientation in the sagittal plane for proposed treatment (A) and actual treatment performed (B).

Table 4
–Multivariate analysis of morphological parameters regarding the effective treatment.

Parameter	*p* value
Height	<**0.001**
Aspect ratio	<**0.001**
Dome diameter	**0.014**
Dome-to-neck ratio	<**0.001**
Maximum diameter	<**0.001**
Size ratio	**0.003**
Dome orientation (anterior vs. non-anterior)	**0.011**
Time until treatment (TUT)	**0.161**

than solely the modified Rankin scale. Unicentric data also hampers any external validity to our results. We compared data in a very large timespan, which understates the importance of learning curve, as well as emerging new devices and technologies for both endovascular and surgical treatment.[24,25] Nevertheless, we stress the importance of our results, as they are the result of the accumulated experience of a multidisciplinary team in a major tertiary hospital center in over a decade. Our patients were found to have no significant differences in clinical outcome either comparing the proposed or effective treatment but the morphological differences among them emphasizes a different subset of patients selected for each treatment modality, underlining the obvious selection bias in a real-world setting and regarding all intracranial aneurysms.[26] Further prospective data with an approximation of the natural history of this disease should bring more insight and matter for consideration when determining a treatment strategy.[27,28]

5. Conclusions

Anterior-projecting aneurysms, larger lesions with higher aspect-ratio, size-ratio and dome-to-neck ratio showed a significant difference towards the endovascular group, showcasing high heterogeneity, possible selection bias and hampering inferential analysis when comparing both techniques.

CRediT authorship contribution statement

Vasco Carvalho: Conceptualization, Formal analysis, Methodology, Writing - original draft. **António Vilarinho:** Conceptualization, Writing - review & editing. **Patrícia Polónia:** Conceptualization, Writing - review & editing. **Maria Luís Silva:** Validation. **Rui Vaz:** Project administration. **Pedro Alberto Silva:** Supervision, Writing - review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abbreviations

AComA: anterior communicating artery
aSAH: aneurysmal subarachnoid hemorrhage
BRAT: Barrow Ruptured Aneurysm Trial
CT: computerized tomography
3D-CTA: tridimensional computerized tomography angiogram
DSA: digital subtraction angiography
ISAT: International Subarachnoid Aneurysm Trial
mFischer: modified Fischer
mRs: modified Rankin scale
TICU: time on intensive care unit
TUT: time until treatment
WFNS: World Federation of Neurosurgical Societies