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Clipping of ruptured intracranial aneurysms in a hybrid room environment—a case-control study

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Abstract
Background Hybrid room treatment (HRT) provides the surgeon immediate intraoperative angiography control of aneurysm occlusion and vessel patency. Since it is relatively resource demanding, in clinical routine HRT is reserved for elective cases. However, since its introduction in our department in 2008, several random cases of ruptured intracranial aneurysms (IAs) have been treated in the HR. This study aims to compare the clinical and radiological outcomes of these cases with cases treated conventionally using a matched pair analysis.
Methods Twenty (20%) consecutive patients with ruptured IA treated by microsurgical clipping in the HR between 2009 and 2015 were retrospectively matched with "conventionally" (C) treated patients (overall $n = 101$). Clinical and radiological outcome variables were assessed and compared.
Results Despite a trend in favor of the HR group, no significant difference between both matched groups (HR vs. C) could be demonstrated regarding the functional outcome (upper/lower good recovery 16/20 vs. 17/20, $p > 0.05$), frequency of clipping-related vascular insults on CT scans (0/20 vs. 3/20, $p > 0.05$), aneurysm remnant rate on postoperative angiography (1/20 vs. 4/20, $p > 0.05$) and retreatment rate (0/20 vs. 1/20, $p > 0.05$). When cumulating all outcome events by a scoring system, however, the HR cohort showed a significantly lower occurrence of events ($p < 0.05$). In three cases co-treatment by an endovascular approach was performed in the HR cohort.
Conclusion In this relatively small cohort, a matched pair analysis revealed a discrete but not significant tendency toward a lower frequency of aneurysm remnants and clipping-related vascular insults in the HR cohort. However, HR cohort patients benefited from direct endovascular co-treatment in selected cases.

Keywords Aneurysm · SAH · Intraoperative angiography · Clipping

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Introduction

Microsurgical clipping of intracranial aneurysms (IAs) aims for complete aneurysm occlusion under preservation of parent and branching vessel patency. In cases of ruptured IAs, local and general bleeding sequelae may further complicate successful achievement of these goals. Different routine *real-time* imaging modalities are available to support the surgeon during the procedure in this regard: micro-Doppler [2, 9, 24], indocyanine green (ICG)-fluorescence angiography [19, 20] and intraoperative digital subtraction catheter angiography (DSA) [5, 15]. While routine intraoperative angiographies are restricted to 2D visualization of structures and (in case of ICG-fluorescence angiography) are limited to already exposed parts of the vasculature, utilization of preinstalled high-speed flat-panel angiography systems provides complete intracranial dynamic vessel imaging in the highest resolution and 3D reconstruction during surgery. Furthermore, endovascular co-

interventions thus become possible. Such a "hybrid" treatment environment has previously been described by our group in detail [22].

In the Department of Neurosurgery of the University Hospital of Geneva, Switzerland, a hybrid room (HR) was installed in 2008 and since then has been mostly used for complex elective neurovascular procedures (mostly because of its resource-demanding mode). However, random single cases of ruptured aneurysms have also been treated in this specific environment.

The present study aims to analyze these consecutive *urgent* cases regarding clinical and radiological outcomes in comparison to a control cohort treated under "conventional" conditions (micro-Doppler, ICG-fluorescence angiography) using a matched-pair design. We tested the hypothesis that HR utilization leads to fewer postoperative aneurysm remnants, fewer postoperative ischemic results by vessel impairment (occlusion, stenosis, kinking) and lower retreatment rates.

Materials and methods

The study was conducted according to the principles expressed in the Declaration of Helsinki and was approved by the local university institutional review board as part of a superordinate study on intracranial aneurysms (Geneva CCER 07–056).

Database research was performed to identify all patients who underwent microsurgical clipping for a ruptured IA in the HR between 2009 and 2015. Patient data were assessed regarding: age, gender, aneurysm localization, aneurysm size [maximum diameter (mm)], aneurysm side, pre-ictus neurological condition (mRankin score), pretreatment neurological condition (WFNS score [4]), severity of the subarachnoid hemorrhage (SAH) (Fisher score) as well as the presence and size of associated intracerebral hemorrhage (ICH) and duration of treatment (min). Afterwards, patients were accordingly matched [age: ±5 years, gender: mandatory equal, localization of IA: mandatory equal, size of IA: ±5 mm, pre-ictus (pre-ictus/treatment neurological condition: mandatory equal, presence/size of ICH: mandatory equal] with a patient who had undergone "conventional" treatment in our department between 2009 and 2015.

General treatment assignment

Ruptured aneurysm treatment decisions were generally based on an interdisciplinary discussion between vascular neurosurgeons and neuro-radiologists in every individual case. As a general rule, aneurysms of the posterior circulation are preferably treated by an endovascular approach while middle cerebral artery (MCA) aneurysms are preferably treated by a microsurgical approach. Anterior communicating artery (Acom) aneurysms and posterior communicating artery (Pcom) aneurysms as well as respective internal carotid artery (ICA) aneurysms are treated by both approaches according to aneurysm neck geometry. Overall, aneurysm location and shape as well as basic patient-specific characteristics determine the definite treatment option in our department.

Hybrid room treatment assignment

Utilization of the hybrid room was desired in all surgical cases; however, the necessary additional technical and medical workforce for the hybrid room was not constantly available. Consequently, the assignment to hybrid room treatment depended on the respective daily or nightly availability of these resources and thus was completely random. A flow chart of the usual treatment assignment can be found in Fig. 1.

Microsurgical treatment modalities

Both cohorts [hybrid room (HR) and conventional (C)] underwent clipping in the typical microsurgical manner (Zeiss Pentero, Zeiss, Oberkochen, Germany) by vascular neurosurgeons (P.B., K.S., I.R., M.J.) using micro-Doppler and ICG-fluorescence angiography control as a routine. In the HR cohort additionally (repetitive) intraoperative flat panel 3D angiography (Philips Allura FD20 system, Philips Medical Systems, Best, The Netherlands) was utilized. Any clip replacements or repositioning based on the intraoperative findings was documented. Duration of treatment was documented.

Postoperative assessment

All patients in the control group underwent 3D digital subtraction angiography in a conventional angiography suite within 48 h, and all patients had computed tomography (CT) within 24 h for treatment control. Clinical condition was assessed at discharge and at least 1 year postoperatively using the modified Glasgow Outcome Scale (GOS) [4].

Imaging

Occlusion of the aneurysm on postoperative angiography was assessed according to the Sindou score [23]. New postoperative hypoperfusion or non-perfusion due to occlusion, stenosis or kinking of any associated vessel branch was assessed. Postoperative CT scan(s) were also analyzed for any post-treatment vascular insults (new hypodensity in the vessel territory/surgical site, new hemorrhage in the vessel territory).

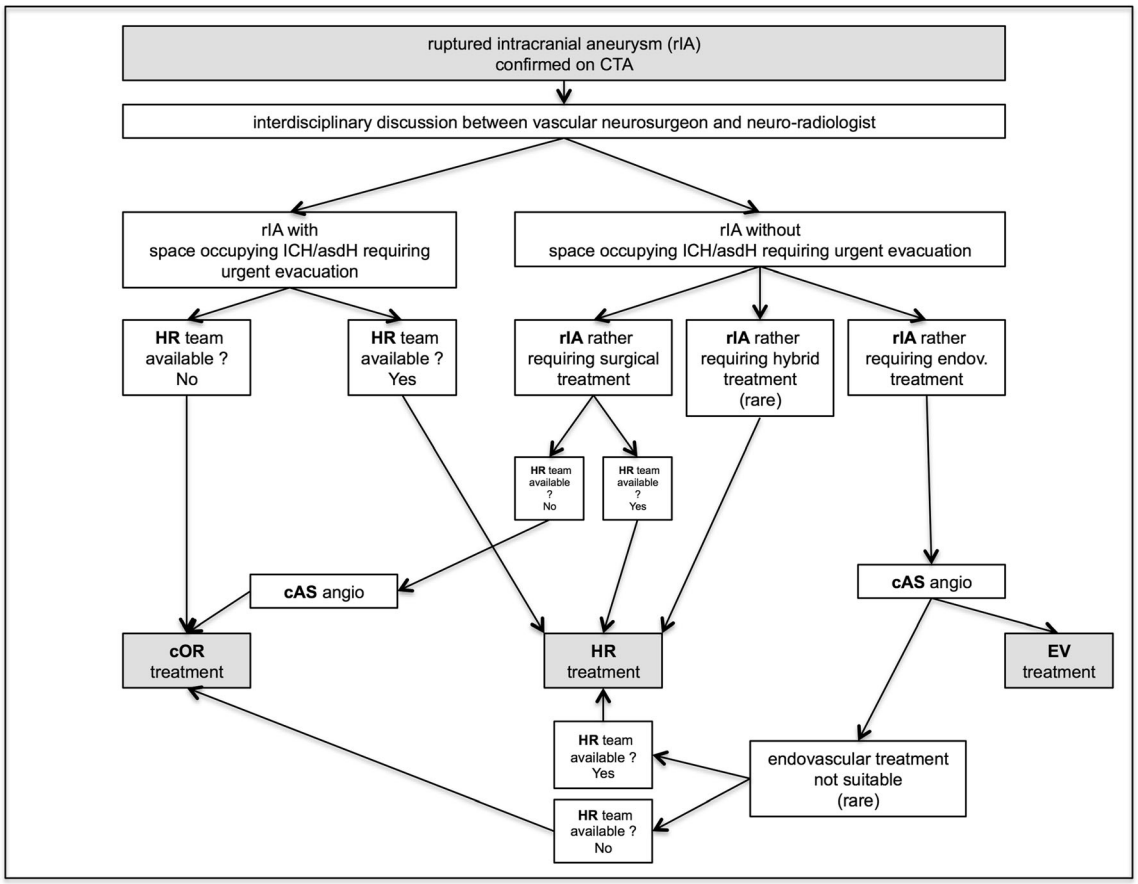

Fig. 1 Flow chart of the usual diagnostic algorithm in patients diagnosed with ruptured intracranial aneurysm. The diagnostic and treatment process is of course sometimes individually modified. cOR = conventional operating room, cAS = conventional angio suite, EV = endovascular

Outcome definition

Outcome was assessed and compared in regard to (1) the aneurysm remnant, (2) loss of an associated vessel branch with consecutive stroke and (3) retreatment and the combination of all features. For the latter we defined a "failure score" to include and weigh the overall outcome impact on the patient: aneurysm remnant without retreatment =1, aneurysm remnant with retreatment =2, vessel occlusion without stroke =1, vessel occlusion with stroke on imaging =2, and vessel occlusion with stroke on imaging and neurological sequelae (functional outcome 1 year postoperatively) =3.

Furthermore, outcome was assessed regarding functional outcome at the 1-year follow-up, mortality and post-treatment infarction rate (CT evidence of infarction during hospital stay, delayed cerebral infarction).

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics 22 (SPSS Inc., IBM Corp., North Castle, NY, USA). Interval-scaled data were expressed as mean and standard deviations, and nominal data were expressed as absolute numbers and valid percent. Data were tested for normal distribution by conducting a Shapiro-Wilk test in addition to histograms and Q-Q plots. We used parametric statistics for between-group comparison for normally distributed data and nonparametric statistics for non- normally distributed data.

Matched-pair results were analyzed by McNemar's test (categorical variables) and Wilcoxon signed-rank test (ordinal scale variables). Power was calculated with an estimated percentage of exposure of 15% and α risk = 5%.

Results

Of 329 patients who presented with SAH due to a ruptured IA between 2009 and 2015, 101 (30%) were treated by microsurgical clipping. Among these, 22 (21.7%) were treated in the HR. This accounts for 4.9% of all aneurysm cases treated in the HR overall (n = 443) in this period. Twenty of these patients could be matched according to the above-mentioned requirements.

Thirteen female and 7 male patients (26–70 years, mean age 50.6 ± 13) presented with SAH due to rupture of an IA [12 middle cerebral arteries (MCA), 5 anterior communicating arteries (Acom), 1 anterior choroidal artery (ant.chor.), 1 pericallosal artery (pc.) and 1 posterior communicating artery (Pcom)]. Aneurysm size ranged between 3 and 25 mm (mean 8.7 ± 5.6 mm). Initial WFNS grades were *I* = 14 (70%), II = 3 (15%) and IV = 3 (15%). Presence of ICH was found in three cases (15%). For comparison of matched pairs, see Table 1.

Radiological outcome

Postoperative angiography revealed overall five (12.5%) aneurysm remnants (Sindou *I* = 2, Sindou III = 2, Sindou IV = 1). One remnant (Sindou I) was found in the HR cohort (5%), four in the C cohort (20%). Vessel occlusion/stenosis/kinking with associated postoperative signs for infarction on CT scan were not found in the HR cohort. In the C cohort this was found in three (15%) cases (2 occlusions, 1 stenosis). The overall rate of any vascular insults after treatment initiation during the hospital stay was 5 (25%) in each group. For between-group comparisons, see Table 2.

Intraoperative angiography findings led to repositioning of clip decisions after initial ICG control in five patients (25%; *n* = 5/20).

Functional outcome

Overall outcome (GOSE) at 1-year follow-up (FU) was GOSE 8 *N* = 23 (58%), GOSE 7 *N* = 9 (18%), GOSE 6 *N* = 5 (10%) and GOSE 4 *N* = 1 (2%). One-year mortality (GOSE 1) was 5% (*n* = 2). Both patients who died belonged to the HR cohort. One patient died from a severe vasospasm and one from a later trauma.

Both groups showed an equal proportion of upper/lower good recovery at 1-year FU [16/19 (84%) vs. 17/20 (85%)]. See also Table 2. No HR angiography-related complications were found in this series.

Retreatment

One patient (5%) in the C cohort underwent endovascular retreatment because of incomplete occlusion (Sindou IV) of the aneurysm.

Combined outcome

Combining all endpoints, remnant rate, vessel occlusion and retreatment rate as surgical failures, interventions performed in the HR environment "failed" a single time as compared to seven cases in the C cohort (OR = 7.00, 95% CI 0.889–315.48, $p = 0.0771$). Using the scoring system built, we found 19 patients scoring 0 and one patient scoring 1 in the HR cohort and 11 patients scoring 0 in the C cohort, 3 patients scoring 1, 3 patients scoring 2 and one patient scoring 3. Wilcoxon signed rank testing (W value) showed a significant difference ($p < 0.05$).

Operative characteristics

In three cases simultaneous co-treatment by an endovascular approach (coiling) was performed in the HR cohort. Clips

Table 1 Comparison of baseline characteristics between the HR and case-control cohorts

Baseline characteristics				
	Overall (*n* = 40)	*HR* cohort (*n* = 20)	*C* cohort (*n* = 20)	
Age [years]	50.5 ± 12.8	50.6 ± 13.9	50.3 ± 12.0	$p = 0.941$[a]
Gender	14 male (35%)	7 male (35%)	7 male (35%)	
Aneurysm location				
MCA	24 (60%)	12 (60%)	12 (60%)	
Acom	10 (25%)	5 (25%)	5 (25%)	
Ant. chor.	2 (5%)	1 (5%)	1 (5%)	
Pericallosal	2 (5%)	1 (5%)	1 (5%)	
Pcom	2 (5%)	1 (5%)	1 (5%)	
Aneurysm size [mm]	8.17 ± 4.99	8.7 ± 5.6	7.6 ± 4.1	$p = 0.482$[a]
Initial WFNS grade				
I	28 (70%)	14 (70%)	14 (70%)	
II	6 (15%)	3 (15%)	3 (15%)	
IV	6 (15%)	3 (15%)	3 (15%)	
ICH present	6 (15%)	3 (15%)	3 (15%)	

HR = hybrid room, C = conventional. [a] Tested by two-sided T-test

Table 2 Comparison of outcomes between the HR and case-control cohorts

Radiological and functional outcome				
	Overall (n = 40)	*HR* cohort (n = 20)	*C* cohort (n = 20)	
Aneurysm remnants				
Overall	5 (12.5%)	1 (5%)	4 (20%)	$p = 0.3711$[a]
Sindou I	2	1	1	OR 4.00
Sindou III	2	0	2	95% CI
Sindou IV	1	0	1	0.396–196.90
Clipping-related vessel occlusion	3 (7.5%)	0	3 (15%)	$p = 0.2482$[a]
Overall vascular insults during hospital stay	10 (25%)	5 (25%)	5 (25%)	
1-year FU mGOS				
8	23 (58%)	10 (50%)	13 (65%)	$p = 0.8231$[a,b]
7	9 (23%)	5 (25%)	4 (20%)	OR 1.000
6	4 (10%)	2 (10%)	2 (10%)	95% CI
5	1 (3%)	0	1 (5%)	0.374–2.677
4	1 (3%)	1 (5%)	0	
3	0	0	0	
2	0	0	0	
1	2 (5%)	1 (5%) (2)[c]	0	
Mortality	2 (5%)	2 (10%)	0 (0%)	$p = 0.4795$[a]
Retreatment rate	1 (2.5%)	0 (0%)	1 (5%)	
Endpoints combined[d]	8 (20%)	1 (5%)	7 (35%)	$p = 0.0771$[a]
				OR 7.000
				95% CI
				0.899–315.48

HR = hybrid room, C = conventional. [a] Tested by two sided T-test. [a] Tested by McNemar's test, when applicable presented with odds ratio. [b] Difference of mGOS 7 and 8; [c] one patient died from a different disease during follow-up; [d] combination of aneurysm remnant, clipping-related vessel occlusion and retreatment

were replaced based on HR angiography findings (after initial ICG-fluorescence angiography) in five cases. All were replaced because of incomplete clipping, vessel stenosis or vessel kinking (for an exemplary case, see Fig. 2). Mean duration of treatment was 231.2 ± 63.29 min in the C cohort and 285.9 ± 90.97 min in the HR cohort, resulting in an overall difference of 54.7 min.

Discussion

Complete occlusion of an aneurysm while preserving normal vessel patency is the aim of microsurgical treatment. Aneurysmal remnants may lead to regrowth and even rerupture [10, 12, 13, 23] while unintended vessel occlusions often lead to neurological sequelae [17]. Different imaging and monitoring techniques are utilized to support the surgeon in the achievement of this aim [21].

The present study aims to analyze the potential benefit of a treatment for ruptured IA performed in a hybrid room [22] with intraoperative flat-panel 3D rotational angiography available in comparison to a "standard" treatment using micro-Doppler and ICG-fluorescence angiography.

Given a relatively small cohort of 20 patients, we used a matched-pair analysis approach to increase comparability and achieved a nearly perfect matching result. Furthermore, all included patients underwent surgery by the same four surgeons, who were equally distributed in both groups. Due to a limited number of patients, further secondary aneurysm-specific factors (configuration of branch vessels, calcification) that may affect microsurgical treatment and treatment outcome were not included in the matching process.

Although not reaching statistical significance, a certain tendency toward better results in the HR cohort regarding the aneurysm remnant rate (1 vs. 4), clipping-related vessel occlusion (0 vs. 3) and retreatment rate (0 vs. 1) was found. Combining all endpoints (remnant rate, vessel occlusion and retreatment rate) as surgical failures, interventions performed in the HR environment failed a single time as compared to seven cases in the C cohort (OR = 7.00, 95% CI 0.889–

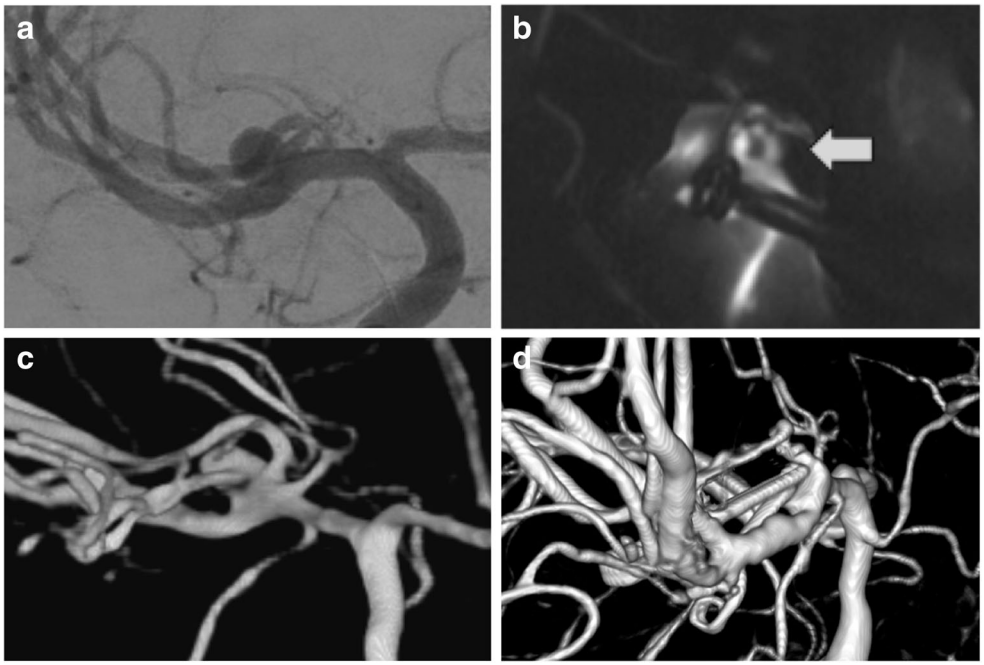

Fig. 2 Exemplary case: Ruptured MCA bifurcation aneurysm on the right side (**a**) showing preoperative angiography and (**b**) showing ICG images after a proximal approach to the aneurysm and clip positioning. Clipping was complicated by intraoperative rupture. Surgeon checking the patency of perforators (big arrow) and aneurysm base. Intraoperative angiography (3D reconstruction) showing an inappropriate clip position with a large dome remnant and perfusion of the anuerysm (**c**). After repositioning and adding another clip, the second intraoperative angiography shows complete occlusion (**d**)

315.48, $p = 0.0771$). In a matched pair analysis with 40 cases (20 cases, 20 controls), assuming 15% exposure and an alpha risk of 5%, the smallest detectable odds ratio is estimated to be 8.17. Hence, detection of a significant difference would have required a very strong effect.

In addition, we could demonstrate a significant difference between the cohorts when applying the above-described summary scoring system, which includes a weighting of how the treatment failures impact the patient (Wilcoxon signed-rank test, $p < 0.05$). Although reflecting in the authors' opinion a common sense evaluation of potential treatment failures, the score is not validated, and its intervals remain arbitrarily chosen.

In contrast to the angiographic outcome, cohorts did not significantly differ in the functional outcome and overall amount of vascular insult rate during hospital treatment (delayed cerebral infarction). In our opinion, this finding reflects the complexity of SAH cases with secondary effects not directly connected to or even decoupled from treatment.

Overall our results are within the range or reported incidences after clipping of the IA (neck residuals 4%–19%, unexpected major vessel occlusions 1%–12% [7]) and functional outcome after SAH [18]. The relatively good functional performance after 1 year FU in our collective may be partially explained by the high proportion of initial WFNS grade I patients in the two cohorts.

Intraoperative treatment control modalities are discussed controversially and depend on various factors such as invasiveness (catheter angiography-related complication rate of approximately 1% [6]), cost-effectiveness and, of course, reliability. In the literature, "gold standard" recommendations by authors have shifted from intraoperative angiography [3, 5, 14] to ICG-fluorescence angiography [7, 11] in the last 2 decades. This was mainly promoted by comparable clinical results combined with lower costs and lower invasiveness of ICG-fluorescence angiography [7, 11]. However, more recent series have also demonstrated some limitations of ICG-fluorescence angiography in the detection of aneurysm remnants (19% remnants not detected, 0.5–4.3 mm, mean 1.8 mm size) [8].

In this series, we systematically analyzed the utilization of an intraoperative 3D rotational angiography (in a hybrid room environment) for the first time. The 3D angiography allows a more precise evaluation of (clipped) intracranial aneurysms than 2D angiography [1, 16, 25] and presumably ICG-fluorescence angiography as well. In a preinstalled setting [22], the imaging work flow is furthermore relatively fast. In our study, hybrid room treatment took roughly 50 min longer than conventional treatment (231.2 ± 63.29 min vs. 285.9 ± 90.97 min).

Although statistical analysis showed no direct significant difference in radiological and clinical outcome, intraoperative angiography findings led to repositioning of clip decisions (after initial ICG control) in this series in one of four patients (25%; $n = 5/20$). These were mainly patients harboring larger aneurysms (8, 10, 14, 18, 25 mm) showing a more complex anatomy and more limited surgical space.

Finally, in this series three patients (15%) benefited from simultaneous endovascular treatment (of additional unruptured IA) sparing additional future interventions. Also, all patients receiving intraoperative clipping control by DSA naturally spare the often routine postoperative DSA clipping control.

Technical and logistical drawbacks

Main drawbacks of hybrid room utilization in our department are not of a technical but mainly of a logistical nature.

In non-elective cases the additional technical workforce necessary for the hybrid room service has to be moved from other medical facilities necessitating the respective approval and availability. For further details on the technical challenges, please refer to the previous publications [22].

Study limitations

A clear limitation of the study is the small sample size making it unlikely to answer the initial hypothesis definitively. A larger cohort will be necessary to validate our preliminary results. Finally, the retrospective approach of the study is accompanied by its typical statistics- and data assessment-related drawbacks.

Conclusion

In this relatively small cohort, a matched pair analysis revealed a lower severity-adjusted "failure rate" in the HR environment and no significant tendency toward a lower frequency of remnants and clipping-related vascular insults in the HR cohort. In addition, HR cohort patients benefited from direct endovascular co-treatment in selected cases.

Compliance with ethical standards

Funding No funding was received for this research.

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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Comments

The authors report a small retrospective experience of treating ruptured aneurysms in a hybrid neurovascular operating room from 2009 to 2015. They compared this group with the traditional operating room management using a novel scale designed by the authors that accounts for both the occurrence of a negative outcome and the severity of such an outcome. They have reduced statistical limitations by performing matching of the cohorts and admit to limitations of the cohort size but provide a nuanced analysis of the outcomes using a scale that accounts for the occurrence as well as severity of negative outcomes. This begins to provide data to determine the utility of hybrid operating suites in neurosurgery.

Although they used the hybrid surgical suite, they have limited the application to the diagnosis of suboptimal clip constructs. This study has only considered the diagnostic utility of high-resolution intraoperative angiography and therefore has not leveraged the potential of hybrid treatment techniques. Even after broader adoption of hybrid treatments, centers will need to report on the economic cost and risks of these tools to establish or refute continued use of this technology. The potential for a beneficial economy is there, in that the cost of a stroke or other vascular complication is high, but this solution will need validation before widespread adoption.

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