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Original Article

Procedure-related Complication Rate for the Endovascular Treatment of Aneurysmal Subarachnoid Hemorrhage under Local Anesthesia

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Objective : To report the procedure related complication rate of endovascular treatments (EVTs) performed on patients with aneurysmal subarachnoid hemorrhage (aSAH) under local anesthesia (LA).

Materials and Methods : This study enrolled 186 patients who underwent EVT for ruptured aneurysm under LA from January 2009 to December 2013. Procedure-related complications rate and factors associated with it were analyzed depending on the patients' factors, aneurysm factors and physician factors.

Results : Among the 186 patients who underwent EVT under LA, the respective rates of thromboembolic complication (TEC) and intraoperative rupture (IOR) were 12.8% (23 cases) and 12.9% (24 cases), respectively. Aneurysm size (≥ 7 mm) was the only risk factor for TEC (p = 0.048).

Conclusion : Compared to previous result with under general anesthesia (GA), the rate of TEC was similar in patients treated under LA, but the IOR rate was significantly higher. The main reason for increasing IOR is considered as the unexpected patients' motion and in accordance with the unexpected movement of the microinstruments. Therefore, another methods to stabilize the patients or switching from LA to GA may be necessary when performing EVT, to reduce complications.

Keywords Subarachnoid hemorrhage, Endovascular procedure, Thromboembolic complication, Intraoperative rupture, Local anesthesia

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INTRODUCTION

The annual incidence of aneurysmal subarachnoid hemorrhage (aSAH) is about nine people per 100,000 population.[2] The population-based mortality of subarachnoid hemorrhage (SAH) is 38%,[8] 10-15% of patients with aSAH die before they arrive at the hospital, and a further 5% of patients die within the first 24 hours after hemorrhage.[17] Obliteration of the ruptured aneurysm is the only effective treatment for SAH. The typical treatments for SAH are surgical clipping and endovascular treatment (EVT). The platinum coils are inserted in the lumen of ruptured aneurysm, and then the local thrombus, formed around the coils, finally obliterates the sac. After the International Subarachnoid Aneurysm Trial (ISAT), EVT with coil is a first-line treatment for managing a ruptured aneurysm.[7][14]

The coil embolization can be performed under local anesthesia (LA) or general anesthesia (GA), and the GA in more common in general.[3] EVT may lead to several complications. The two most common EVT procedure-related complications are thromboembolic complication (TEC) and intraoperative rupture (IOR).[13)15)] Both of these complications are somewhat more common in the setting of SAH than for unruptured aneurysm.[16)] As proven, these two procedure-related complications (TEC, IOR) have a significant effect on the mortality and morbidity of aSAH patients,[5)21)] studies of the various risk factors associated with TEC and IOR have continued.[6)12)14)] However, most research studies were performed under GA. There are currently few studies about the relationship of procedure-related complications with LA.

In our hospital, we performed EVT on patients with aSAH under LA. There are currently few studies about complications and risk factors under LA, so we analyzed the results of patients who underwent EVT under LA in our hospital from 2009 to 2013 and compared these results with those of patients who underwent the same procedure under GA.

MATERIALS AND METHODS

This study enrolled 189 patients who underwent EVT for ruptured aneurysm with LA in one institute between January 2009 and December 2013. The study subjects include all patients who had obvious aSAH identified by computed tomography (CT), magnetic resonance imaging (MRI), or lumbar puncture, and who had suspected rupturing intracranial aneurysm in digital subtraction angiography (DSA) or CT angiography and were judged able to be treated by EVT. We performed surgical clipping under GA in 3 patients since we were unable to proceed with coil embolization under LA due to their uncooperativeness even after administration of intravenous sedatives such as Ativan (lorazepam) or Midacum (midazolam), but there was no case of coil embolization under GA. Aborted embolization was excluded in this study. Thus, a total of 186 patients were analyzed.

Three endovascular surgeons performed the procedures, which was performed under LA. The patients' heart rate, electrocardiographic data, blood pressure, respiratory rate, and oxygen saturation were continuously monitored. The procedure was performed under LA with puncture site simple lidocaine infiltration. Intravenous sedatives was considered whilst monitoring patient's vital signs when the patient complains of pain or discomfort, increased heart rate or high blood pressure was noted, or the patient was unable to maintain immobility. Patients with stupor or worse conscious level were likely to show unstable respiratory function and, therefore, underwent the procedure aided by endotracheal intubation.

For all 186 patients, we checked whether there were complications (TEC, IOR). Then, complication rate and risk factors were analyzed with respect to the following factors: patient related factors (age, sex, hypertension, diabetes mellitus [DM], chronic kidney disease [CKD], hyperlipidemia, smoking, previous antiplatelet use, and SAH grade); aneurysm-related factors (aneurysm neck size, aneurysm greatest diameter, and aneurysm height-to-neck ratio); physician- and technique-related factors (whether the single catheter technique or additional techniques such as stent assist embolization or double catheter technique was used).

The aneurysm neck size was defined as wide if the aneurysm neck size was 4 mm or larger, and narrow if it was less than 4 mm. Aneurysm greatest diameter was defined as large if the greatest diameter was 7 mm or larger, and small if it was less than 7 mm. The aneurysm height-to-neck ratio was defined as favorable when the ratio was 1.5 or greater and unfavorable when it was less than 1.5. SAH was graded by the Hunt-Hess grading system. 'Good grade' and 'poor grade' were defined by the grade 1 to 3 and 4 to 5, respectively.

TEC were identified during procedure with angiography regardless of type (thrombus formation near the neck of the aneurysm, thromboembolism in the distal branches, and parent vessel occlusion). Postoperative thromboembolic events were diagnosed with MRI and/or DSA, which were performed in the case of sudden neurologic compromise. IOR was diagnosed if the tip of the coil or microcatheter was seen outside the limit of the aneurysmal sac and/or there was extravasation of the contrast material.

Logistic regression analysis was performed to determine the factors that affected complication incidence. Statistical analysis was carried out using SPSS version 20.0 software (IBM SPSS Inc., Armonk, NY, USA), and significance was determined at $p < 0.05$.

Table 1. Patient and aneurysm characteristics

Variable	No. of patients
Age	
≥ 65	53 (28.5)
< 65	133 (71.5)
Sex	
Female	122 (65.6)
Male	64 (34.4)
Hypertension	
Yes	61 (32.8)
No	125 (67.2)
DM	
Yes	21 (11.3)
No	165 (88.7)
CKD	
Yes	1 (0.5)
No	185 (99.5)
Hyperlipidemia	
Yes	5 (2.7)
No	181 (97.3)
Smoker	
Yes	42 (22.6)
No	144 (77.4)
Previous antiplatelet drug	
Yes	16 (8.6)
No	170 (91.4)
Aneurysm location	
ICA	57 (30.6)
ACA/AcomA	84 (45.2)
MCA	22 (11.8)
VB	20 (10.8)
ICA dorsal wall	3 (1.6)
Neck size	
≥ 4 mm	51 (27.4)
< 4 mm	135 (72.6)
Greatest diameter	
≥ 7 mm	55 (29.6)
< 7 mm	131 (70.4)
Height-to-neck ratio	
≥ 1.5	101 (54.3)
< 1.5	85 (45.7)
SAH grade	
Good grade	156 (83.9)
Poor grade	30 (16.1)

Values are presented as number (%).
DM = diabetes mellitus; CKD = chronic kidney disease; ICA = internal carotid artery; ACA = anterior cerebral artery; AcomA = anterior communicating artery; MCA = middle cerebral artery; VB = vertebrobasilar system; SAH = subarachnoid hemorrhage

RESULTS

The study sample was composed of 64 men (34.4%) and 122 women (65.6%). Patients' mean age was 55.5 ± 13.74 years old, and 133 patients (71.5%) were under 65 years. Sixty-one patients (32.8%) had hypertension and 21 patients (11.3%) had DM. In addition, 42 patients (22.6%) were smokers and 156 patients (83.9%) had good grade.

The aneurysms were located in the internal carotid artery (ICA) in 57 (30.6%), anterior cerebral artery (ACA)/anterior communicating artery (AcomA) in 84 (45.2%), middle cerebral artery (MCA) in 22 (11.8%), vertebrobasilar system (VB) in 20 (10.8%), and dorsal wall of the ICA in three patients (1.6%).

The aneurysm neck size was wide in 51 (27.4%) and narrow in 135 patients (72.6%). The aneurysm size was small in 131 (70.4%) and large in 55 patients (29.6%). The height-to-neck ratio was favorable (≥ 1.5) in 101 (54.3%) and unfavorable (< 1.5) in 85 aneurysms (45.7%) (Table 1).

Procedure-related complications (TEC or IOR) occurred in 47 cases (25.3%) and among these, TEC occurred in 23 cases (12.4%) and IOR occurred in 24 cases (12.9%) (Table 2).

In the analysis of patient-related factors that affected the outcome, age, sex, hypertension and DM have no statistically significant correlation with TEC and IOR. In addition, CKDs, hyperlipidemia, smoking, previous antiplatelet medication and SAH grade also did not show statistically significant correlation (Table 3).

Table 2. Frequency of TEC and IOR events

Variable	No. of patients	Previous studies
Incidence of TEC & IOR	47 (25.3)	
TEC	23 (12.4)	11.0-12.5[12)14)]
IOR	24 (12.9)	2.5-5.0[5)6)19)]

Values are presented as number (%).
TEC = thromboembolic complication ; IOR = intraoperative rupture

Table 3. Patients related risk factors of TEC and IOR

Variable	Complications		TEC		IOR	
	No.	*p* value (OR, 95% CI)	No.	*p* value (OR, 95% CI)	No.	*p* value (OR, 95% CI)
Age		0.682 (0.861, 0.372-1.992)		0.540 (0.721, 0.239-2.169)		0.985 (1.005, 0.337-2.998)
≥ 65	15 (28.3)		8 (15.5)		7 (13.2)	
< 65	32 (24.1)		15 (11.3)		17 (12.8)	
Sex		0.493 (1.346, 0.630-2.876)		0.263 (1.796, 0.665-4.850)		0.905 (0.986, 0.358-2.715)
Female	29 (23.8)		13 (10.7)		16 (13.1)	
Male	18 (28.1)		10 (15.6)		8 (12.5)	
Hypertension		0.732 (0.840, 0.382-1.846)		0.958 (0.944, 0.329-2.714)		0.692 (0.786, 0.289-2.133)
Yes	17 (27.9)		9 (14.8)		8 (13.1)	
No	30 (24.0)		14 (11.2)		16 (12.8)	
DM		0.387 (0.605, 0.193-1.886)		0.632 (0.711, 0.172-2.935)		0.445 (0.566, 0.127-2.515)
Yes	7 (33.3)		4 (19.0)		3 (14.3)	
No	40 (24.2)		19 (11.5)		21 (12.7)	
CKD		1.000		1.000		1.000
Yes	0 (0.0)		0 (0.0)		0 (0.0)	
No	47 (25.4)		23 (12.4)		24 (13.0)	
Hyperlipidemia		0.360 (0.398, 0.050-3.203)		0.145 (0.222, 0.028-1.742)		0.999
Yes	2 (40.0)		2 (40.0)		0 (0.0)	
No	45 (24.9)		21(11.6)		24 (13.3)	
Smoking		0.573 (0.816, 0.360-1.851)		0.713 (0.834, 0.283-2.458)		0.705 (0.844, 0.294-2.423)
Yes	12 (28.6)		6 (14.3)		6 (14.3)	
No	35 (24.3)		17 (11.8)		18 (12.5)	
Previous antiplatelet drug		0.241 (0.419, 0.095-1.846)		0.945 (1.056, 0.218-5.131)		0.998
Yes	44 (25.9)		20 (11.8)		24 (14.1)	
No	3 (18.8)		3 (18.8)		0 (0.0)	
SAH grade		0.500 (1.286, 0.532-3.110)		0.770 (1.093, 0.329-3.636)		0.552 (1.386, 0.465-4.131)
Good grade	38 (24.4)		19 (12.2)		19 (12.2)	
Poor grade	9 (30.0)		4 (13.3)		5 (16.7)	

Values are presented as number (%).
TEC = thromboembolic complication; IOR = intraoperative rupture; OR = odds ratio; CI = confidence interval; DM = diabetes mellitus; CKD = chronic kidney disease; SAH = subarachnoid hemorrhage

In the correlation analysis of outcome factors with aneurysm-related factors such as aneurysm neck size, greatest diameter, and height-to-neck ratio, neck size and height-to-neck ratio did not show a significant statistical correlation with the occurrence of TEC and IOR. However, aneurysm greatest diameter showed a significant correlation with TEC occurrence; the TEC occurrence rate was 21.8% for those with a large aneurysm and 8.4% for those with a small aneurysm ($p = 0.048$). Also, the location of the aneurysm did not show a statistically significant correlation with procedure-related complications (Table 4).

Three surgeons performed 55 (29.6%), 94 (50.5%), and 37 (19.9%) EVT cases, respectively. There was no significant statistical difference in complications between the three surgeons. Regarding technique factor, there was no significant difference between the groups who underwent single catheter coil embolization and those who used additional techniques such as stent-assisted coil embolization or double catheter coil embolization (Table 5).

DISCUSSION

Prior to the introduction of the endovascular coil in the 1990s, craniotomy and surgical clipping was a standard treatment for cerebral aneurysm.[7] Recently, endovascular coiling has become the gold standard in aneurysm treatment, as endovascular coiling has shown greater stability and better outcomes in ISAT and other studies.[7][10][11]

However, EVT can cause some complications during the procedure; the endovascular procedure-related complications of SAH include device failure, coil migra-

Table 4. Aneurysm related risk factors of TEC and IOR events

Variable	Complication		TEC		IOR	
	No.	*p* value (OR, 95% CI)	No.	*p* value (OR, 95% CI)	No.	*p* value (OR, 95% CI)
Aneurysm location		0.111 (0.744, 0.518-1.070)		0.081 (0.628, 0.372-1.058)		0.742 (0.927, 0.590-1.456)
ICA	17 (29.8)		10 (17.5)		7 (12.3)	
ACA/AcomA	22 (26.2)		10 (11.9)		12 (14.3)	
MCA	5 (22.7)		2 (9.1)		3 (13.6)	
VB	3 (15.0)		1 (5.0)		2 (1.0)	
ICA dorsal wall	0 (0.0)		0 (0.0)		0 (0.0)	
Neck size		0.605 (0.918, 0.663-1.270)		0.891 (1.027, 0.699-1.510)		0.410 (0.818, 0.508-1.318)
≥ 4 mm	13 (25.5)		8 (15.7)		5 (9.8)	
< 4 mm	34 (25.2)		15 (11.1)		19 (14.1)	
Greatest diameter		0.113 (2.142, 0.836-5.489)		0.048* (3.126, 0.964-10.137)		0.843 (1.138, 0.318-4.076)
< 7 mm	29 (22.1)		11 (8.4)		18 (13.7)	
≥ 7 mm	18 (32.7)		12 (21.8)		6 (10.9)	
Height-to-neck ratio		0.478 (0.761, 0.358-1.618)		0.735 (0.841, 0.308-2.292)		0.505 (0.719, 0.273-1.896)
≥ 1.5	25 (24.8)		13 (12.9)		12 (11.9)	
< 1.5	22 (25.9)		10 (11.8)		12 (14.1)	

Values are presented as number (%).
TEC = thromboembolic complication; IOR = intraoperative rupture; OR = odds ratio; CI = confidence interval; ICA = internal carotid artery; AcomA = anterior communicating artery; ACA = anterior cerebral artery; MCA = middle cerebral artery; VB = vertebrobasilar system.
* Significant correlation by univariate analysis, $p < 0.05$

tion, dissection, etc., and the most frequent complications are TEC and IOR.[7,12,21] The incidence of TEC and IOR have been reported in 11-12.5%[12,14] and in 2.5-5%[5,6,19] of patients who underwent EVT, respectively. The major causes of TEC are distal vascular thrombosis formation caused by the original thrombus of vessel wall tearing by microcatheter or microwire, local thrombosis formation, and emboli shedding after procedure.[21] The incidence of IOR is related to the microcatheter, or guide-wire, as well as oversizing the coils, overpacking the aneurysm, or using stiff three-dimensional coils.

In general coil embolization of aSAH was carried under GA. The advantage of EVT under GA is that we can perform interventions in optimal conditions. This results in fewer technical failures and complications, therefore obtaining better clinical outcomes.[1] But endovascular coil embolization could be carried without GA because it does not involve extensive surgical excision. Coiling under LA allows us to evaluate a patient's neurological status intra-procedurally. In addition, it can lower the additional risks associated with GA and mechanical ventilation, such as cardiopulmonary morbidity rates, hospital stay length,

Table 5. Physician and technique related risk factors of TEC and IOR events

Variable	Complication		TEC		IOR	
	No.	*p* value (OR, 95% CI)	No.	*p* value (OR, 95% CI)	No.	*p* value (OR, 95% CI)
Physician		0.858 (1.045, 0.643-1.700)		0.287 (0.692, 0.351-1.363)		0.217 (1.488, 0.791-2.801)
Physician 1	13 (22.8)		8 (14.0)		5 (8.8)	
Physician 2	26 (28.3)		14 (15.2)		12 (13.0)	
Physician 3	8 (21.6)		1 (2.7)		7 (18.9)	
Technique		0.475 (1.404, 0.554-3.557)		0.131 (4.871, 0.624-38.005)		0.580 (0.743, 0.260-2.127)
Single catheter						
Additional	7 (20.6)		1 (2.9)		6 (17.6)	
Technique	40 (26.3)		22 (14.5)		18 (11.8)	

Values are presented as number (%).
TEC = thromboembolic complication; IOR = intraoperative rupture; OR = odds ratio; CI = confidence interval

and hospital costs.[4] And emergency coil embolization with GA is not always possible in real clinical field. As mentioned earlier, several studies reported the complication rate of EVT, but they are confined to that performed under GA only. However, few studies have examined complication rates for procedures carried out under LA. In our hospital, from the time of the first EVT, we performed EVT under LA for all cases. Therefore, we studied how procedure-related complications and factors affecting complications differed under LA compared to GA.

The incidence of TEC in our study was 12.4%, showing a similar incidence to previous studies.[12)14)] However, the incidence of IOR was 12.9%, which was more than double compared with other studies (2.5-5%).[5)6)19)] This was a visible part of the notable differences with other studies performed under GA, and could be viewed as the effects of the type of anesthesia.

The most likely cause of IOR is perforation by a microcatheter and microwire.[20)] Discomfort at the femoral cannulation site, severe headache, hot sensation upon injection of contrast into the cerebral artery and the electrolysis of the detachable coils in the procedure can cause pain.[9)] Long procedure time could be stressful for patients[9)] and poor patient cooperation due to hemorrhage could cause movement. These factors could cause the movement of the microcathter or microwire, by moving the patient, these may lead to the IOR during the coil embolization under LA.

These reasons mean that there is always the possibility of movement of the patients and changes in vital signs. As changes and movement could be unpredictable under LA, operators might be less able to concentrate on the procedure itself. And these unstable factors may cause impatience to the operators, and they also enable you to make the wrong decision during procedure. For most patients in this study, there was unexpected movement of the head. This is thought to be the reason why IOR showed a higher incidence under LA. On the other hand, reducing patients' movements with GA could achieve a lower rate of complications. In the same principle, TEC rate was expected to be higher compared to the GA. But in this study, TEC rate was similar to that of the others studies.[12)14)] This is probably because the rate of TEC was so high as over 10 % that the rates under GA and LA did not differ.

Patient-related factors that are known to influence the incidence of TEC or IOR during coil embolization are as follows: smoking, absence of hypertension, and age under 65 years.[14)] However, none of the aforementioned factors along with other patients factors, such as patients' gender, DM, CKD, previous antiplatelet treatment and SAH grade, had a significant correlation with the complication in this study.

Aneurysmal factors were also reported to affect the occurrence of TEC and IOR. The incidence of TEC was higher when the aneurysm was 10 mm or larger at its greatest diameter, and when the neck was 4 mm or wider.[6)14)18)] In addition, the incidence of IOR was higher when the aneurysm was located in a MCA bifurcation, and the aneurysm's greatest diameter was less than 7 mm.[12)14)] In this study, the only factor related to TEC occurrence was the greatest diameter of the aneurysm, and the other factors did not show a significant relationship with TEC. The IOR was not significantly correlated with any patient-related or aneurysm-related factors. A larger aneurysm was a risk factor for TEC in this study, the same as the results of previous studies.[6)14)18)] For large aneurysms, a lot of intra-aneurysmal clotting prior to EVT and a larger clot volume induced by coil occlusion in the aneurysm may elevate the risk of TEC.[14)] Unlike other studies,[14)] a wide neck aneurysm was not a significant risk factor for TEC. A previous study explained the reason for the higher TEC rate in wide neck aneurysms as it required a large coil surface, which has a higher potential for thrombus formation, higher possibility of intra-aneurysmal clot migration, and a higher risk of coil protrusion into the parent vessel.[14)] However, this does not show statistical significance in our study; it is difficult to describe the clear reason.

There were also some limitations to our study. First, the number of population was not high enough. It is difficult to generalize the results due to the insufficient number of patients available for analyzing how patients' factors affected procedure complications. Second, a comparison between a GA group and a LA group was not performed at the one institute; differences between institutes may have affected outcomes. Third, differences in the time before performing EVT and time taken for EVT for each patient might have affected the results. Fourth, there was a potential selection bias, because patients were selected on a case-by-case basis. Lastly, the subjects in our study were not randomized, with adverse events being self-reported. Nevertheless, there was an obvious difference in the complication rate for EVT in accordance with the type of anesthesia used.

CONCLUSION

Compared to GA, the TEC rate was similar for patients treated under LA, but the IOR rate was significantly higher. It is necessary another local anesthetic technique that reduce patients movement by reducing the pain and anxiety of the patients. If not, switching from LA to GA may be necessary to reduce complications and to improve outcomes.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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