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RESEARCH ARTICLE

MECHANICAL THROMBECTOMY WITH TEMPORARY BYPASS USING SOLITAIRE FR STENT FOR TREATMENT OF ACUTE PROXIMAL MIDDLE CEREBRAL ARTERY THROMBOSIS

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Abstract

Objectives: We present the efficacy of mechanical thrombectomy with temporary bypass technique in management of proximal middle cerebral artery thrombosis at the acute phase of cerebral ischemia using Soiltaire FR Stent.

Material and Methods: It is a retrospective study that include five patients presented with cerebral ischemia at the acute phase and which were eligible for a mechanical thrombectomy. We evaluate the population, the ischemic criteria on initial and post-therapeutic MRI, the technique, and the angiographic and clinical results of mechanical thrombectomy.

Results: Angiographically, we noticed a mean progression of the TIMI score from 1 to 2.4, a mean decrease of NIHSS clinical score of 12 points and one localized asymptomatic intraparenchymatous hemorrhage.

Conclusion: The mechanical thrombectomy with temporary endovascular bypass technique using the Soiltaire FR stent represents an efficient novel strategy to achieve the recanalization of an occluded proximal middle cerebral artery and an amelioration of the clinical state.

Introduction:-

The early restitution of the flow is a crucial factor in the clinical outcome of ischemic stroke treated at the acute phase (Asadi et al., 2016). Currently, numerous studies demonstrated that chemical thrombolysis with combined intravenous and intra-arterial injection could be partially ineffective (Klisch et al., 2015). That is why mechanical thrombectomy is potentially a necessary complementary technical method (Chandra et al., 2017). Thus, many strategies concerning endovascular thrombectomy have been developed and tested recently (Goldstein et al., 2016). But despite the diversity of devices available, complete recanalization of middle cerebral artery was achieved in approximately half of the cases (Goyal et al., 2016). In addition, some of these techniques are time consuming, difficult in achievement and generate side effects (Jovin et al., 2015).

Some recent studies report the use of intracranial self-expanding and reconstrainable stents as an effective treatment of the acute ischemic stroke (Dumont et al., 2014).

These stents are usually used for the treatment of intra-cerebral aneurysms or less frequently intracranial atherosclerotic disease (Spiotta et al., 2015). We report our initial experience with the use of the Soiltaire FR stent

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as a temporay bypass for recanalisation of acute intracranial vessel occlusions (Borhani et al., 2014). We retrospectively identified five patients admitted with occlusion of the middle cerebral artery refractory to treatment with chemical thrombolysis by intravenous injection at the effective dose. These patients were treated with delivered and deployed (up to 100%) Soiltaire FR stent across the thrombus to restore an arterial flow (bypass) and then removed as thrombectomy device. This technique seems to combine the advantages of intracranial stenting without exposing the patient to the risks caused by intracranial implantation of a permanent device (thrombosis or potential side effects of anti-thrombotic treatment) (Dash et al., 2014),(Ghosal et al., 2014).

Materials and Methods:-

Patients (table 1)

Our study is a retrospective analysis of a group of five patients (three women and two men) treated between 01/2017 and 01/2019 for an acute ischemic stroke affecting the middle cerebral artery.

The inclusion criteria for mechanical thrombectomy with temporary bypass stenting were:

1. Delay between onset of symptoms and treatment is less than four and a half hours.
2. Confirmation of acute ischemia on MRI (Diffusion restriction with decrease of the ADC).
3. Occlusion of the middle cerebral artery detected in MRA,
4. Clinical inefficiency of chemical intravenous thrombolysis.
5. Radiological inefficiency of chemical thrombolysis detected during angiography.

Methods:-

All five patients have been admitted directly to our Stroke Unit. A clinical examination confirmed the deficit and collects the clinical history and comorbidities. The initial NIHSS score was established during this step. A MRI was performed immediately (Figures 1 and 2). The examination was realized on a 1.5T MRI PHILIPS (Achieva 2.1, Best, Netherlands). The exporation included the following sequences: Diffusion with ADC mapping, axial T2 GE, axial FLAIR, axial T1, 3D TOF, and a CE-MRA (Dotarem, Guerbet, Aulnay-sous-Bois, France). The MRI confirmed ischemia and its acute nature with systematized diffusion restriction (middle cerebral territory) on the DWI sequence, with a correlative decrease of the ADC. The non-enhanced angio-MR sequence (3D TOF) confirmed obstruction of the proximal (M1 segment) middle cerebral artery (MCA). CE-MRA allowed us to analyze the size of thrombus and the state of the downstream cerebral perfusion by collateral branches as well as to perform a mapping of the supra-aortic arch (helpful for selection of catheters for arteriography).

The patients then received an intravenous chemical thrombolysis (Actilyse®, Alteplase, Boehringer, Ingelheim, France) at effective dose (0.9 mg / kg).

In the situation of not responding to intravenous treatment, patients were requested written consents for enrolling to mechanical thrombectomy group.

For all five patients, angiography and thrombectomy with use of Soiltaire FR stent was performed under local anaesthesia. An introducer 6 F was placed into the femoral artery. A 6-F Envoy (Codman Neurovascular) guiding catheter was then placed in the internal carotid artery. Selective injection confirmed the presence of an occlusion of the MCA and studied the collateral supply. Then, in case of a persistent MCA occlusion and no response to intravenous thrombolysis, selective catheterization of the MCA was performed with a Rebar® 18 microcatheter (Covidien, Irvine, California) beyond the occlusion site. Deployement (up to 100%) of the Soiltaire FR stent (Covidien, Irvine, California) for 5-10 minutes was performed across the site of occlusion, creating a temporary bypass. The length of stents used was 26 mm in the 5 cases. After a control angiography, the Soiltaire FR system was retrieved as a thrombectomy device. This manoeuvre was associated with an aspiration with a 20 ml syringe through the guiding catheter in order to obtain a flow inversion in 4 cases. After removal of the stent, angiography was done to control the permeability of the MCA (Figure 4).

Twenty four hours later, a clinical examination and CT scan was performed to evaluate the post-therapeutic NIHSS score and eliminate hemorrhagic transformation.

Three days later, a new MRI was realized to control the extent of ischemia, confirm the recanalization of the MCA and to ensure the absence of complication.

Statistics

All demographic and clinical factors and NISHH score were collected for the five patients (Table1). We analyzed the MRI: ischemic territory (deep, superficial or total middle cerebral territory), the site of the MCA occlusion (proximal or distal) (Table 2). Then we specified the duration of thrombectomy with the calculation of the delay between the femoral puncture and the confirmation of a satisfactory flow in the MCA, the number of deployments of the stent needed to obtain this result, and the possible use of complementary therapies (Nimodipine, angioplasty or other thrombectomy devices)(Table 3).

We analyze as well, the arteriographic flow restoration or revascularization with the TIMI and TICI score at the beginning and the end of the procedure (Table 4).

Finally, we analyzed the efficacy and safety of the technical data relating to clinical examination and the control MRI performed three days later (Table 5).

Clinical outcome was evaluated at 3 months with modified Rankin Scale (mRS).

Results:-

The average patient age at the beginning of treatment was 43.8 years [19-61]. The mean base line NIHSS score at the admission was 15.6 [10-20].

In the five cases, the diffusion sequence confirmed the presence of ischemia with a decrease in the ADC in the middle cerebral artery territory. The ischemia was localized in the deep territory in two patients, the superficial territory in one patient and the whole territory in the last two patients. The 3D TOF sequence confirmed and localized arterial obstruction. It was located at the proximal portion of M1 in four patients and distal in the last case. No contraindication (bleeding, extended ischemia or symptom onset > 6 hrs) to thrombolysis has been highlighted on the sequences Flair and T2 GE.

Finally, the grade of collateral circulation and occlusion was evaluated using TIMI and TICI score after DSA. In all cases, the occlusion was complete with a minimal (1) TIMI or a TICI score (Table 2).

In the five patients the final angiographic control showed satisfactory recanalization of the MCA with a favorable evolution of TICI and TIMI score (the average TIMI scores 1 at the beginning of procedure evoluting to 2.4 at the end. Immediate revascularisation was achieved after a single passage means deployement and retrival of the stent in four patients. Two passes were required for one patient. The average delay between the femoral puncture and confirmation of a satisfactory flow within the stent was estimated at 28 minutes (20-35 minutes depending on the patient).

Three days after the procedure, clinical outcome was favorable in the five patients with an significant NIHSS score improvement. The mean NIHSS score at 3 days was 3.2 (from 0-12) with an improvement of 12.4 points in this series of 5 patients. The control MRI showed in all cases no significant extension of ischemia the sequence of diffusion. In one patient of 29 years, a small area of T2 GE hyposignal, was found three days after the procedure. This hemorrhagic transformation was asymptomatic (Table 4).

No complications were detected in the four other patients.

The CE-MRA confirmed the recanalization of the middle cerebral artery and the corresponding cerebral revascularization at 72 hours).

We reviewed 4 patients after 3 months. From the group of 5 patients one died during 3 months follow up (Table 6). We have no data concerning the origin of his death.

Discussion:-

Stroke is the third cause of mortality, the second cause of dementia and the first cause of disability (Ma et al., 2015). The annual incidence of stroke is 2.4 in 1000, with 15-20% mortality during the first month and 75% of sequels (Nam et al., 2015). The acute ischemic stroke is 80% of cases while hemorrhagic stroke is about 20%. About 80% of

ischemic strokes affect the carotid distribution (within the middle cerebral territory in 70% of cases) (Saver et al., 2015). Physiopathologically, the ischemia is secondary to abolition or reduction of blood flow through a cerebral artery. In most cases, this interruption is due to a cardiogenic origin (20%) or cervical atherosclerotic plaque (25%)(Carcora et al., 2015).

The occlusion of a cerebral artery is responsible of a lower in cerebral blood flow inside the territory concerned (Jadhav et al., 2015). Normal cerebral blood float is advanced to 50 ml consistent with one hundred mg of mind tissue. Thus, during the acute phase of stroke, three zones may be defined: crucial vicinity wherein blood goes with the flow is decrease than 10ml/100mg and in which ischemia is irreversible, then a bordering quarter of "ischemic penumbra", wherein the glide is among 10 and 15 ml/100mg, and eventually a peripheral ring of oligemia. In these final regions, the lesion can be reversible if dealt with swiftly (Ji et al., 2015).

So, the main issue in the management of cerebral ischemia at the acute phase is the fast recovery of areas of penumbra and oligemia to limit the ischemia extension (Patel et al., 2017). When there is an acute stroke, the severity of the deficit depends on three factors: the degree of obstruction, its duration and the vulnerability of the underlying parenchyma. Several studies reported a significant correlation between favourable clinical outcome and effectiveness of reperfusion (rate and delay) (Ma et al., 2017).

The management of acute ischemia is constantly changing. Actually, the FDA recommendations for the chemical intravenous thrombolysis are a therapeutic window up to four hours and a half after the onset of symptoms (Goyal et al., 2015). Intravenous thrombolysis may be insufficient, especially for proximal occlusion of large intracranial vessels (25% success for the MCA proximal occlusions) (Protto et al., 2016). The intra-arterial delivery of thrombolytics agents to the site of occlusion increases the rate of successful recanalization (the rate of recanalization of the M1 occlusions was 66% in the PROACT-II study) (Lemmens et al., 2016). Combined intravenous and intra-arterial chemical thrombolysis may however be insufficient to complete the reopening of the vessel (67% in the IMS study) (Campbell et al., 2015). Thus, the mechanical thrombolysis appears to be a satisfactory complement to allow revascularization and reperfusion. Furthermore, this allows expanding the therapeutic window to six hours after the beginning of the episode.

Penumbra® and MERCI® devices are currently approved by the FDA. The rate of partial and complete recanalization with the use of one device was only 54% without chemical thrombolysis (Gory et al., 2014). Combined with intra-arterial rt-PA the rate increases to 70%. But the concomitant use of intra-arterial thrombolytic agents, were improving this rate, but generating an increased number of hemorrhagic transformations (Berkhemer et al., 2015).

The self-expandable stents (Solitaire, Soiltaire FR and Leo) have a recognized application for the vascular reconstruction of aneurysms. Several studies report the use of these devices for recanalization of occluded intracranial vessels (Campbell et al., 2015).

The Soiltaire FR stent, when positioned properly across the thrombus), can be open circumferentially and displace the clot, immediately creating a channel of flow within the occluded vessel. Once flow is reestablished, the high local concentration of prothrombotic factors in the region of thrombus is washed out, simultaneously; there is an increase of fibrinolytic physiological conditions favorising recanalization (Gory et al., 2014).

In addition, the Soiltaire FR stent, if completely deployed can be fully reintegrated into its sheath and recaptured. This allowed us to use it as a mechanical thrombectomy device. Indeed, during its deployment, the stent exerts a concentric force against the thrombus which is then trapped between the stent and the vessel wall (Saver et al., 2015). After the five to ten minutes of use as a temporary bypass, we could imagine that the thrombus will be impacted within the mesh of the stent, and may therefore remove with it. Indeed, a second use of the stent was required only once while the MERCI study related a mean number of five to six passes. (Jovin et al., 2015)

The system of self-expanding stent (Leo, Solitaire, and Soiltaire FR) provides the advantage of being able to deploy without balloon, thereby reducing the risk of trauma to the vessel wall, and thus intracranial dissection (Asadi et al., 2016). The microcatheter Rebar® 18 (Covidien, Irvine, California) designed for stent delivery has a good navigability adapted to cerebral vessel anatomy.

Use of the Soiltaire FR stent seems to be an effective treatment for symptomatic occlusion of the proximal middle cerebral artery. Indeed, being able to remove the device reduces the risk of secondary stenosis into the stent and eliminates long-term use of anti-platelet, thereby reducing the short, medium and long term risk of bleeding (Goldstein et al., 2016). In addition, the vascular obstruction is most often secondary to a thrombosis of a healthy intra-cerebral vessel by an embolus, so, it does not seem necessary to leave a permanent material within the artery after removal of the clot (Gory et al., 2014).

Furthermore, compared to other thrombectomy devices, intracranial stent seems more easily usable. Indeed, the system requires a 6-F and not a 8-F guiding catheter such as Merci system, which makes navigation often easier within atherosclerotic carotid vessels (Protto et al., 2016). This ease of use is illustrated by the short time between the femoral puncture and the recanalization of the occluded middle cerebral artery. This delay has been estimated to average 28 minutes for our five patients. A study on the use of the Penumbra reported within 40 minutes (Zibold et al., 2016). Another study reported within 50 minutes with the system SolitaireFR (Bhole et al., 2015). The difference of delay presumably comes from the use, for some patients in these studies, of the stent system as a "rescue" after failure of other devices. This also easier navigation enables a relatively simpler use for a single operator, which can be useful for emergencies.

The most important advantage of Soiltaire FR stent when used for this type of pathology arises from that can be completely deployed, then withdrawn (Powers et al., 2015).

The limitations of our series is the small number of patients. Moreover, we didn't use other thrombectomy devices such aspiration catheter which seems to be easier to use, because it was not available in our department.

Conclusion:-

Use of mechanical thrombectomy with temporary bypass technique with the Soiltaire FR stent seems to be an interesting therapeutic option to achieve immediate recanalization of the occluded vessel and reperfusion of brain tissue. It is effective and avoids the risks and disadvantages associated with permanent stent implantation.

Patient	Age	Sex	Comorbidities	NIHSS on admission
1	19	F	Nephrotic Syndrome	2
2	29	F	Lupus erythemtosus	20
3	52	M	HTN, Dyslipidmia	7
4	61	M	HTN, AF	9
5	58	F	HTN	10

Table 1:- Characteristics of the population.

Patient	Age	Site of ischemia	Site of occlusion
1	19	deep	proximal
2	29	total	proximal
3	61	total	proximal
4	52	deep	distal
5	58	deep	proximal

Table 2:- Initial MRI

Age	Number of passes	Delay	Associated Treatment
19	1	32	Non
29	2	20	Nimodipine+angioplasty
61	1	34	Non
52	1	25	Non
58	1	30	Non

Table 3:-thrombectomy.

TICI (initial)	TIMI (initial)	TICI (final)	TIMI (final)

1	1	3	3
1	1	2b	3
1	1	2b	3
1	1	3	2
1	1	2a	2

Table 4:-Analyse of the flow restoration: TIMI and TICI classification at the beginning and the end of the procedure.

Patient	Death	Haemorrhage	Vasospasm	NIHSS
1	0	0	1	3
2	0	1	1	0
3	0	0	0	12
4	0	0	0	0
5	0	0	0	1

Table 5:-Clinical and radiological outcome: clinical examination and MRI at 3 days.

Patient	GOS	mRS
1	5	0
2	4	1
3	1	6
4	5	0
5	5	0

Table 6 :-Clinical outcome at 3 months.

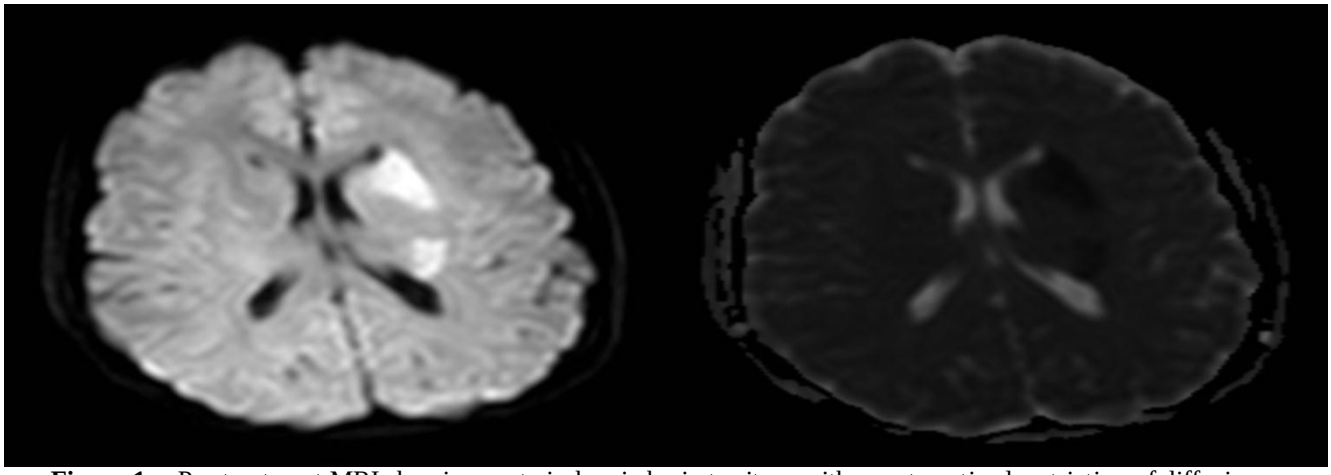


Figure 1 :- Pre-treatment MRI showing acute ischemic brain territory with a systematized restriction of diffusion sequence (A) and a correlate decrease of ADC (B).

Figure 2 :-MRI 3D TOF (A) angiogram sequence illustrating proximal occlusion of M1 segment of left middle cerebral artery, and angio-MRI angiogram with injection (B) confirming occlusion and allowing visualization of thrombus and downstream traffic.

Figure 3 :-Angiography and thrombectomy: confirmation of occlusion of the left M1 (A), crossing the microcatheter through the thrombus (B), and Soiltaire FR stent with restoration of flow within the MCA, "Bypass" effect (C).

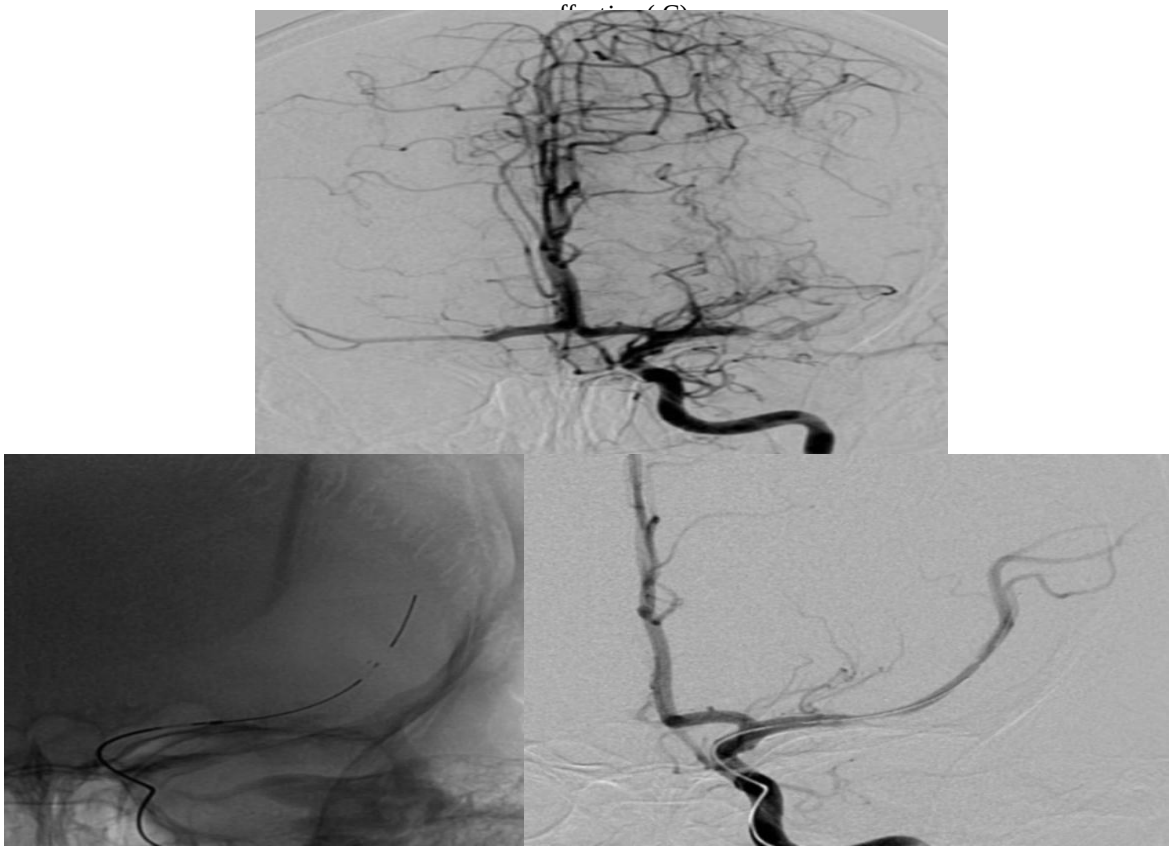
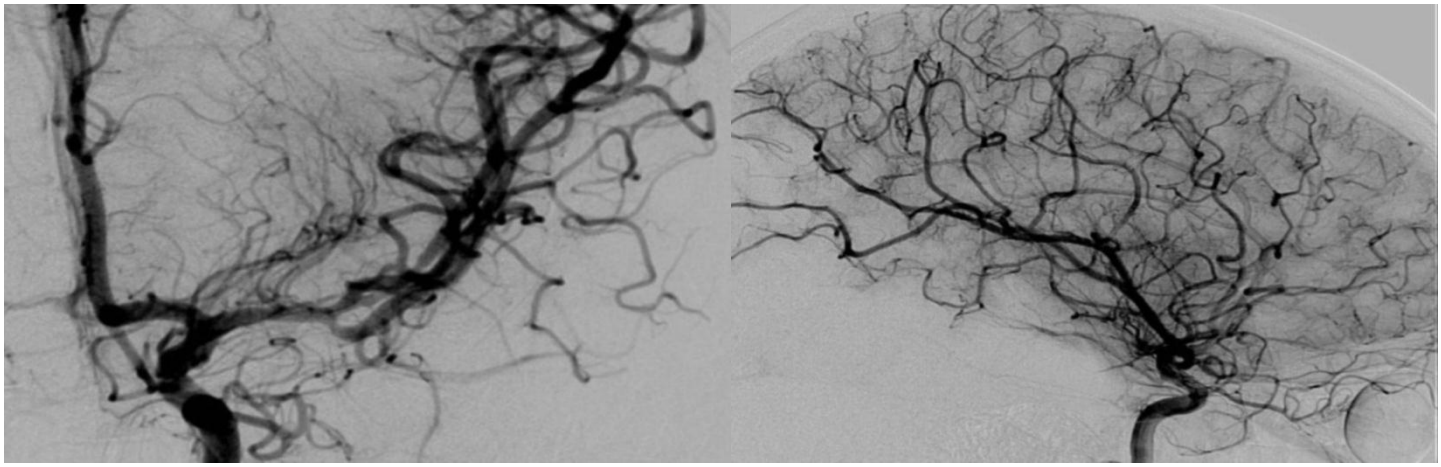


Figure 4 :-Control Angiography, A-P (A) and lateral (B) views, end of procedure confirming satisfactory recanalization of left MCA and branches.



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