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Article

Comaneci-assisted coiling of wide-necked intracranial aneurysm: A single center preliminary experience

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Abstract: Background: Wide-necked aneurysms are still challenging both for coiling and microsurgical clipping. They often require additional techniques to prevent coil prolapse into the parent artery, such as balloon-assisted and stent-assisted coiling. Comaneci is an expandable and removable stent that acts as a bridging device and does not interfere with the blood flow of the parent artery. Methods: We retrospectively reviewed our institutional radiological and clinical chart of the patients treated for saccular intracranial aneurysm via endovascular coiling Comaneci-assisted. The aim of the study is to report our preliminary experience in Comaneci-assisted coiling of wide-necked intracranial aneurysms. Results: We included 14 patients, 11 with a ruptured intracranial aneurysm, that were treated with Comaneci-assisted coiling. Five minor intraprocedural complications and 2 intraprocedural failure of the device were registered. At one year follow-up a satisfying aneurysm occlusion has been observed in 85% of the cases. Conclusion: Even if longterm follow-up data and larger case series are needed, this preliminary study showed the feasibility of the Comaneci-assisted coiling for both ruptured and unruptured wide-neck intracranial aneurysms, with similar occlusion rate to balloon-assisted coiling. However we registered high incidence of thromboembolic complications probably related to the lack of heparin administration. The main advantage of this technique is likely in cases of ruptured intracranial aneurysms, as there is no need for post-procedural antiplatelet therapy.

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Keywords: Comaneci; assisted-coiling; intracranial aneurysm; embolization

1. Introduction

Even if endovascular treatment of intracranial aneurysms has been widely performed for both ruptured and unruptured intracranial aneurysms [1–3] supporting and replacing surgical treatment, wide-necked aneurysms (WNAs) are still a challenging morphological type of aneurysm.

The endovascular coiling for WNAs is associated with a high risk of coil mass protrusion into the parent vessel and consequent ischemia of the downstream territories [4]. Indeed, in comparison with narrowed-neck aneurysms, endovascular embolization of WNAs is associated to higher procedural risks and poorer long-term follow-up [4]. To

avoid coil prolapse and major ischemic iatrogenic complications, WNAs usually require additional techniques, such as balloon-assisted coiling (BAC), stent-assisted coiling (SAC), or the application of a flow diverter stent or the emerging endosaccular devices [5-8]. These additional techniques may increase the risk of thromboembolic complications during the procedure and, in certain cases, require dual antiplatelet therapy [9-11]. Both BAC and SAC are currently implied in the treatment of WNAs to protect the parent vessel in either a temporary or permanent fashion [12,13]. However, BAC temporarily obstructs flow, meanwhile the use of stents necessitates dual antiplatelet therapy that increases procedural as well as long-term bleeding risks [14,15].

We describe our early experience with Comaneci bridging device in the treatment of both ruptured and unruptured WNAs. The main advantage of this novel technique is the possibility to perform a temporary bridging on the neck aneurysms without the blood flow occlusion and its intrinsic soft structure may reduce the risk of vessel rupture, compared to the remodeling balloons, and it does not required dual antiplatelet therapy (DAPT), as a self-expanding stent, as it is fully removable.

The aim of the study is to retrospectively describe our early experience with Comaneci bridging device in the treatment of both ruptured and unruptured WNAs in 14 patients.

2. Methods

This is a monocentric study. We retrospectively collected the patients with WNAs treated for saccular intracranial aneurysm via endovascular Comaneci-assisted coiling. We collected patients since our first institution case in October 2015 and May 2021. The Comaneci-assisted coiling was performed by two senior operators of 12 and 6-year of experience at the moment of the end of the enrollment. The Comaneci (Rapid Medical, Yokneam, Israel) bridging device is a controllable, nondetachable, and retrievable temporary bridging device recently introduced to assist in the coiling process [16–19]. As a bridging device, the Comaneci does not interfere with the blood flow of the parent artery and it can be expanded according to the aneurysm neck morphology and vessel requirement [17]. The Comaneci device consists of three device models: Comaneci, Comaneci Petit, and Comaneci 17 which are adaptable respectively for vessel diameters of 1.5 - 4.5 mm, 1.5 - 3.5 mm and 0.5 - 3 mm. The device consists of a nitinol fine wire mesh region at the distal end mounted on a flexible shaft that expands and contracts directly when the handle with a control slider is opened and closed. The wires of the mesh are radiopaque, which allows great visibility under fluoroscopy. The Comaneci has a flexible and soft distal tip which allows safe navigation into the vessel.

WNAs have been defined as an aneurysm with an absolute neck width >4 mm or a dome-to-neck ratio of <2 mm. All medical records and imaging were revised. The neurological assessments at discharge and at 3-months follow-up were evaluated by modified Ranking scale (mRS). 3-months magnetic resonance imaging and 1- year digital subtraction angiography was performed. The Modified Raymond-Roy Occlusion Classification was used to classify the aneurysmal status.

The primary goals of our retrospective collection were to assess the safety of Comaneci measured by the number of complications after the procedure; the efficacy of Comaneci, measured by the required deployment of a stent or the need of microsurgical conversion; the thromboembolic risk evaluated as the number of intraprocedural thromboembolic events.

Antiplatelet and antithrombotic management

The protocol of antiplatelet and anticoagulant medications was variable depending on the SAH. Prior 100 mg Acetylsalicylic acid and 75mg/day Clopidogrel, for 5 days before the endovascular embolization, were provided for patients with unruptured aneurysms (in anticipation in case of treatment failure and permanent stent placement

needing). The DAPT was discontinued after the procedure if the Comaneci-assisted embolization was successful. Among the patients with ruptured aneurysms, no preventive antiplatelet therapy was provided. In both cohorts, according to our institution protocol, no intravenous heparin was administered, all the catheters were continuously perfused with saline infused with heparin (1500 UI/L), no intravenous heparin was infused. In our institution we prefer continuous flushing of the catheters with heparin during aneurysm embolization that, according to our experience, reduces the risk of clot formation inside the catheters.

Endovascular procedure

All the procedures were performed through right femoral artery access. Through a 7F catheter placed in ICA or Vertebral artery, two microcatheters were used: one 0.017" microcatheter for aneurysm catheterization and one 0.021" or 0.017" microcatheter for the positioning of the Comaneci in the parent artery.

In all cases a three-dimensional rotational angiography (3D-DSA) was performed and the images were evaluated to determine the correct coils and Comaneci size.

First a 0.021" microcatheter, for the Comaneci and Comaneci Petit, or a 0.017" microcatheter, for Comaneci 17, was navigated in the parent artery, then a 0.017" microcatheter was navigated in the aneurysm sack (Figure 1). The Comaneci was then open until a satisfying neck bridging was obtained and the coil was then positioned into the sack (Figure 1). Before the detachment of every coil, the Comaneci was close to evaluate the stability, the correct intrasaccular disposition of the coils, and to exclude the embedding of the coils through the Comaneci. A post-procedural CT was performed in every patient to exclude any periprocedural complication.

3. Results

Population

We included 14 patients diagnosed with saccular intracranial aneurysms who received Comaneci-assisted endovascular coiling. Nine (64%) were female and the mean age was 62.3 years (range 45-86 years) (Table 1).

Eleven (79%) patients were admitted with subarachnoid hemorrhage (SAH), 1 (7%) patient had a persistent headache, 1 (7%) patient had a post clipping growing neck remnant, and 1 (7%) patient was occasionally diagnosed during magnetic resonance imaging (MRI) screening for familiarity. Seven aneurysms (50%) were of the anterior communicating artery (ACom), 5 (36%) of the communicating internal carotid artery (ICA), 1 (7%) in the anterior medullary segment of the posteroinferior cerebellar artery (PICA) and 1 (7%) in the middle cerebral artery (MCA). The mean aneurysm height was 5.83 mm (range 2-14.5 mm), and the mean maximal width was 4.33 mm (range 2-15.6 mm), with mean neck size of 3.14 mm (range 2-8.2 mm).

Case	Age	Sex	Location	SAH	Max size (height, width, neck) mm	Device	Complications	Rescue treatment	mRR	3-months mRs
1	74	F	PCOM	No	4.2, 7, 4	Comaneci	-		I	0
2	65	M	PCOM	Yes	3.1, 4, 3	17	-		I	0
3	70	F	PICA	Yes	3.5, 2, 1.5	Comaneci	-		I	0
4	86	F	PCOM	Yes	6.4, 4.3, 5.5	Comaneci	Intra-Comaneci and parent artery clot formation	Stent	II	6

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5	59	F	ACOM	Yes	10, 6.2, 5.5	17	-		II	0
6	65	F	PCOM	No	6.7, 3.9, 3	Petit	-		II	0
7	51	F	MCA	No	2, 2.2, 2	Petit	-		II	5
8	65	M	ACOM	Yes	5.7, 3.7, 3.5	17	-			0
9	77	F	PCOM	Yes	8, 10.3, 5.9	Comaneci	Intra-Comaneci clot formation		I	0
10	65	F	ACOM	Yes	3, 2.4, 2	17	-		I	5
11	45	M	ACOM	Yes	5.5, 3.6, 2.8	17	Intra-Comaneci clot formation		III b	1
12	62	F	ACOM	Yes	9, 4.5, 3	17	Intra-Comaneci clot formation	Stent	III b	0
13	55	M	ACOM	Yes	14.5, 15.6, 8.2	17	-		I	0
14	61	M	ACOM	Yes	3, 5.9, 5	17	Intra-Comaneci clot formation		II	0

Table 1. Included patients ordered chronologically. Demographic characteristics of the patients and aneurysm characteristics, device used and operative outcome. ACOM, anterior communicating artery; PICA, posterior inferior cerebellar artery; MCA, middle cerebral artery; PCOM, posterior communicating artery.

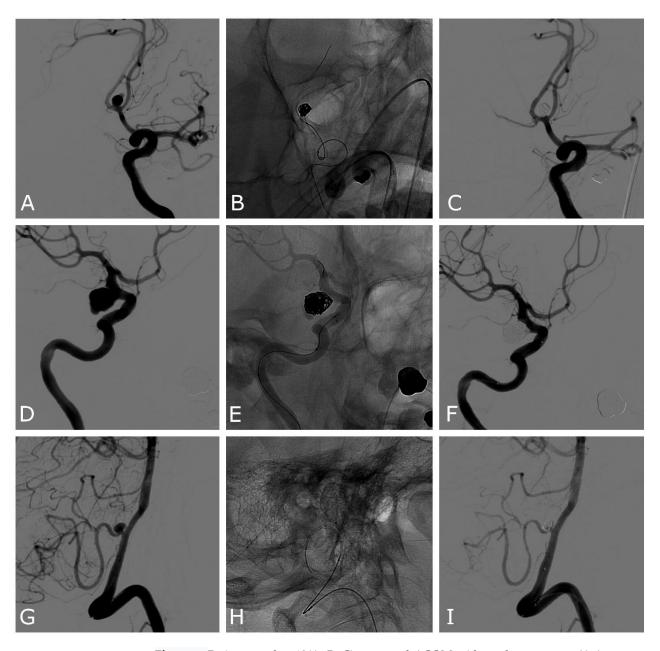


Figure 1. Patient number 13(A, B, C): ruptured ACOM wide-neck aneurysm. A) Anteroposterior oblique 2D DSA demonstrating the ACOM aneurysm with a daughter sac pointing superiorly. B) Unsubtracted image showing the expanded Comaneci after the first framing coil is deployed. C) DSA final result demonstrating complete occlusion of the aneurysm and patency of both the ACA. Patient number 5 (D, E, F): unruptured PCOM wide-neck aneurysm. D) Lateral oblique 2D DSA demonstrating the PCOM aneurysm. E) Unsubtracted image showing the expanded Comaneci after the first framing coil is deployed. F) DSA final result demonstrating near-complete occlusion of the aneurysm, with a small neck remnant in the inferior part and patency of ICA. Patient number 3 (G, H, I): ruptured PICA wide-neck aneurysm. G) Lateral oblique 2D DSA demonstrating the PICA aneurysm. H) Unsubtracted image showing the expanded Comaneci and the 0.017" microcatheter in the aneurysm sack. I) DSA final result demonstrating complete occlusion of the aneurysm, with a small neck remnant in the inferior part and patency of PICA. DSA, digital subtracted angiography; PCOM, posterior communicating artery; ICA, internal carotid artery; ACA, anterior cerebral artery; ACOM, anterior communicating artery; PICA, posterior inferior cerebellar artery.

We deployed 4 (29%) standard Comaneci, 8 (57%) Comaneci 17 and 2 (14%) Comaneci Petit. No navigation or deployment problems have been observed. In 12 (86%) patients Comaneci was able to be deployed to successfully bridge the aneurysmal neck, in 2 (14%)

patients Comaneci did not perform a satisfying scaffolding on the neck of the aneurysm and a self-expandable stent was required.

Modified Raymond-Roy Occlusion Classification (Table 1) achieved at the final angiographic images was Class I in 6 (43%) cases; Class II in 5 (36%) cases and Class IIIb in 2 (14%) cases. No migration of the Comaneci was observed during its expansion or vasospasm in the parent artery. In all the cases an excellent visualization of the device was observed.

Complications

At least an intraprocedural complication was observed in 5/14 patients (35%) (Table 1). In 3/14 (21%) cases we observed clot formation inside the mash of Comaneci (Figure 2), rapidly regressing to the administration of 500mg of Acetylsalicylic acid and Tirofiban (dose by weight, bolus infusion in 30 minutes followed by 12 hours infusion). In 2/14 (14%) cases after infusion of 500mg Acetylsalicylic acid and Tirofiban by scheme the deployment of a rescue Atlas stent (Stryker Neurovascular, Salt Lake City, UT, USA) (Figure 2) was necessarily followed by 1 month of DAPT and subsequent 3 months of Acetylsalicylic acid 100mg/die. In one of the cases where a rescue Atlas stent was released, we had a failure of the Comaneci which was not able to perform a sufficient scaffold on the aneurysm neck and, during the attempt of embolization, we observed intra-Comaneci clot formation and a SAC was immediately performed. In the other case the Comaneci-assisted embolization was performed but coils protruded on the aneurysm neck and intra-Comaneci clot formation was observed, we than the released an Atlas stent to ensure the parent vessel patency. Notably all the complications reported occurred in ruptured aneurysms in which no antiplatelet drugs were administered before the embolization.

In all cases, at imaging follow-up no ischemia was observed documented by strict CT follow-up for at least 30 days after the embolization. No intraprocedural bleeding or delayed aneurysm bleeding was observed.

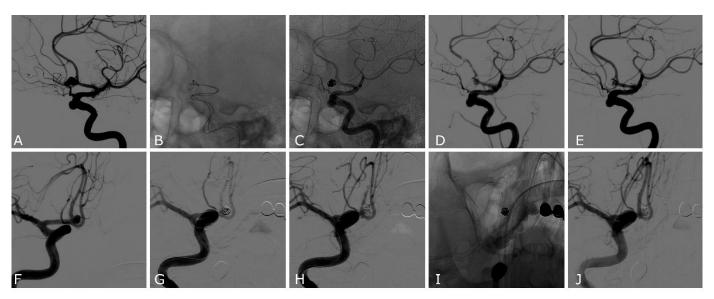


Figure 2 Patient number 11 (A, B, C, D, E): ruptured ACOM wide-neck aneurysm. A) Lateral oblique 2D DSA demonstrating the ACOM aneurysm with a daughter sac pointing anteriorly. B, C) Unsubtracted image showing the expanded Comaneci during the coiling. D) Lateral oblique 2D DSA showing the clot formation between the mashes of Comaneci that required the infusion of Acetylsalicylic acid and Tirofiban. E) Lateral oblique 2D DSA acquired 30 minutes after the infusion of Acetylsalicylic acid and Tirofiban demonstrating a complete resolution of the thrombotic complication and a neck remnant of the aneurysm. Patient number 12 (F, G, H, I, J): ruptured ACOM wide-neck aneurysm. F) Anteroposterior oblique 2D DSA demonstrating the ACOM aneurysm. G) Anteroposterior oblique 2D DSA demonstrating clot formation between the mashes of Comaneci that required infusion of Acetylsalicylic acid and Tirofiban. H) Anteroposterior oblique 2D DSA after

removing the Comaneci showing the protrusion of the coils in the parent artery and thromboembolic occlusion of the right A2 segment of anterior cerebral artery not yet responsive to medical treatment. I) Unsubtracted image of the deployment of a rescue Atlas stent. J) Anteroposterior oblique 2D DSA acquired 30 minutes after the infusion of Acetylsalicylic acid and Tirofiban, demonstrating the patency of the Atlas stent, the resolution of the clot and the patency of both anterior cerebral arteries.

Follow-up

In a range between 12 and 18 months, DSA follow-ups were performed, 10 (71%) patients had a complete aneurysm occlusion, 2 (14%) had a small neck remnant that did not require any further endovascular or microsurgical intervention, 1 (7%) had revascularization of the aneurysm sack and required the deployment of a flow diverter stent (FDs). 13/14 (93%) patients had 3 and 6 months CT that demonstrated no delayed aneurysm bleeding and the appearance of acute or chronic ischemic lesions. Clinical status at 3-months, assessed by mRs we observed good outcome (mRs 0-2) in 11 (79%) patients, poor outcome (5-6) in 3 (21%) patients (Table 1). Among the patients with poor outcome 2 had a ruptured intracranial aneurysm and developed severe intracranial vasospasm, 1 patient had a pretreatment mRs of 5 and no worsening of mRs was observed.

4. Discussion

Despite our preliminary experience, our results show the feasible use of Comaneci device as a temporary bridging device in the coil-assisted treatment of WNAs. Since its approval Comaneci device has been implied in different modalities and different cerebrovascular pathologies [20-22].

Comaneci-assisted embolization ranks between BAC and SAC. Both for BAC and SAC, the aim is to assist the coils' deployment while preventing coils' herniation into the parent vessel [23,24]. BAC involves the temporary vessel occlusion by the inflation of the balloon across the neck of an aneurysm, while SAC involves the placement of a self-expanding stent to support the coils across an aneurysm neck [24]. Although both methods have been demonstrated safe and efficient, BAC may be preferable in some clinical situations because it does not routinely require antiplatelet therapy, [23] although in tortuous anatomy the navigability of the balloon may be a limit. The Comaneci-assisted coiling owns both BAC and SAC characteristics: it has the advantage to perform a temporary bridging effect as the balloon avoids the flow occlusion as a self-expanding stent. These advantages may induce a lower risk of thromboembolic events, in addition its intrinsic soft structure may reduce the risk of vessel rupture during the assisted embolization compared with balloons that present a stiffer structure. However, a potential limitation of the Comaneci is the impossibility to block the blood flow in the event of an intraprocedural rupture. Although Comaneci does not require antiplatelet therapy, it has been described its tendency to clot formation. Sikarov et al. [25] demonstrated an incidence of 5.93% intra-Comaneci clot formation all rapidly regressing with abciximab infusion. Molina-Neuvo et al. [26] and Fisher et al. [17] observed respectively 1.7% and 7.1% of clot formation. In our initial experience, although we experience 35% clot formation. The higher incidence we observed, compared with the previous studies [16, 18, 19, 25], may be related to the lack of intravenous heparin administration. We observed thrombotic complications only in the group of ruptured aneurysms, in which neither antiplatelet nor anticoagulant were administered; meanwhile in the unruptured group, in which DAPT was previously administrated, no thromboembolic complication occurred. We believe that intravenous heparin administration may reduce the incidence of thrombotic complications as it may reduce platelet activation on the Comaneci mashes. Although we observed thrombotic complications in 5 patients, rapidly regressing after medical therapy, no ischemic lesion had been demonstrated during the first month follow-up strict CT and clinical follow-up, except in one patient where severe and unresponsive diffuse intracranial vasospasm occurred. Although we were not able to perform an MRI and we might have underestimated the

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ischemic lesions, all the patients did not reported any symptoms related to the complications. While it has been observed the risk of embedding the coil through the Comaneci mashes [18,26], we did not observe it in any procedure. This risk may be reduced by closing the Comaneci before the detachment of every coil and, if a protrusion of the coils has been observed, the recovery of the coil and a new deployment is mandatory. We observed a satisfying occlusion rate of 86% at follow-up. This rate is similar compared with BAC but lower compared with SAC [27-29]. However, in our series we observed a higher rate of complication than BAC and SAC [27-29] this may be related to our early experience and the small cohort. Compered to our experience with other embolization techniques in ruptured WNAs such as SAC and FDs we observed a higher incidence of thromboembolic complication with Comaneci-assisted coiling. In our experience the incidence of thromboembolic complication with SAC is 6% and 11% with FDs however the rebleeding rates were higher in both groups, 8% and 11% respectively. Compared with the aforementioned techniques we observed a higher incidence of thromboembolic complication with Comaneci but we did not experience any rebleeding. The real advantage of Comaneci compared with a self-expandable stent is the no needing of antiplatelet therapy that, especially in ruptured intracranial aneurysm, may reduce the severity of a possible rebleeding and allows a safer clinical and neurosurgical management of SAH.

In agreement with the results of this study, the Comaneci-assisted coiling is a feasible technique in case of wide-necked intracranial aneurysm. Although in our study we demonstrated an unclear safety of the procedure, given the high incidence of thrombotic complication. We believe to avoid and reduce this risk, according to the previous studies, anticoagulation is mandatory especially in ruptured aneurysms. However studies with a greater number of cases are needed to support the preliminary evidence that emerged in this study and to define more clearly the possible periprocedural complications. The best application of this technique is likely in cases of ruptured intracranial aneurysms, as there is no need for post-procedural antiplatelet therapy.

Limitations

The main limitations of this study are its retrospective nature, with a small number of patients and lack of long-term follow-up. Furthermore, the absence of a BAC control group limits our ability to extrapolate the efficacy of Comaneci-assisted coiling.

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