Early Experience with Comaneci, a Newly FDA-Approved Controllable Assist Device for Wide-Necked Intracranial Aneurysm Coiling

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**Keywords**
Aneurysm · Coil embolization · Comaneci · Bridging device

**Abstract**

**Background:** Comaneci (Rapid Medical) is a compliant, adjustable mesh that provides temporary scaffolding during coiling of wide-necked intracranial aneurysms (WNAs) that preserves antegrade flow. We report our early multi-institutional experience with the Comaneci device in the USA.

**Method:** We reviewed all patients with WNAs that were treated using the Comaneci device for coil remodeling of ruptured and unruptured aneurysms at 4 institutions between July 2019 and May 2020. Clinical characteristics, angiographic variables, and endovascular results were assessed.

**Results:** A total of 26 patients were included (18 women). The mean age was 62.7 years (range 44–81). Fifteen patients presented with ruptured aneurysms and 11 with unruptured aneurysms. The mean aneurysm neck width was 3.91 mm (range 1.9–6.5) with a mean dome-to-neck ratio of 1.57 (range 0.59–3.39). The mean maximum width was 5.80 mm (range 3.0–9.9) and the mean maximum height was 5.61 mm (range 2.0–11.8). Successful aneurysm occlusion was achieved in 25 of 26 patients. Complete occlusion was achieved in 16 patients, near-complete occlusion was observed in 9 patients, and 1 patient demonstrated residual filling. The mean time of device exposure was 24 min (range 8–76). No vasospasm was observed at the device location. Clot formation on the device was noted in 2 separate cases, but there were no clinical sequelae. There was 1 intraprocedural complication in a case that involved the simultaneous use of 2 Comaneci devices.

**Conclusions:** Our initial experience shows that the Comaneci device is a promising and reliable tool that can safely support coil remodeling of WNAs.

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**Background and Introduction**

Wide-necked intracranial aneurysms (WNAs) are among the most difficult vascular lesions to treat. Historically, these aneurysms were mainly treated with mi-
crosurgical clipping, whereas those with narrow necks were considered more favorable for endovascular coiling [1]. The randomized, multicenter International Subarachnoid Aneurysm Trial demonstrated that there was a significant risk reduction after endovascular repair of ruptured aneurysms in comparison with surgical clipping and that there was long-term independence after the procedure [2]. Over time, the embolization of aneurysms in many institutions has become the frontline treatment option [3, 4]. However, WNA s continued to present a greater challenge for coiling because of the risk of the coil mass protruding into the parent vessel as well as lower long-term occlusion rates [5]. Technological advancements have been introduced to assist in coiling of these lesions. Both balloon-assisted coiling (remodeling technique) and stent-assisted coiling are favored in the treatment of WNA s because they protect the parent vessel while coiling in either temporary or permanent fashion (stents with and without deployment) [6, 7]. However, balloon-assisted coiling temporarily obstructs flow, while the use of stents necessitates dual antiplatelet therapy, which carries increased procedural as well as long-term bleeding risks [8, 9]. The Comaneci assist device is a controllable, non-detachable, and retrievable temporary bridging device that is used to assist in the coiling process [10–14].

In April 2019, the Comaneci embolization assist device (Rapid Medical, Yokneam, Israel) received US Food and Drug Administration classification Class II as a temporary coil embolization assist device. Although the device is new to the US market, it has been used with success previously in Europe and Israel [11–14]. As a bridging device, the Comaneci does not interfere with blood flow of the parent artery at the aneurysm neck base but can be expanded according to the aneurysm neck morphology.

**Fig. 1.** Unruptured MCA aneurysm. Wide neck involving mainly the inferior division. **a, b** 3D reconstruction of the right ICA. **c** Lateral oblique 2D DSA demonstrating the MCA aneurysm with a daughter sac pointing superiorly. **d, e** Unsubtracted angiograms showing inflated Comaneci while the first framing coil is pushed and after the last coil is deployed into the aneurysm. **f** DSA final result demonstrating complete occlusion of the aneurysm. MCA, middle cerebral artery; ICA, internal carotid artery.
and vessel requirement [11]. Our objective was to provide further data regarding the use of the Comaneci embolization assist device after Food and Drug Administration approval in the USA.

**Methods**

We undertook a retrospective review of patients with WNAs treated for intracranial aneurysms via endovascular coiling with the assistance of the Comaneci (Fig. 1) at 4 institutions in the USA between July 2019 and May 2020. WNAs were defined as having an absolute neck width >4 mm or a dome-to-neck ratio of <2. The only inclusion criterion was the use of the temporary bridging device. After the patients were identified, we reviewed all medical records and images taken during the procedure and periprocedural periods at the site hospitals. The primary end points of our retrospective review were (1) procedure success as measured by a lack of complications after the procedure, (2) the need to retreat the aneurysm with stent placement, and (3) thromboembolic events. Our secondary end point was the efficacy and effectiveness of Comaneci devices in a real-world setting.

**Results**

**Subject Demographics and Aneurysmal Characteristics**

We identified 26 patients diagnosed with intracranial aneurysms who received Comaneci-assisted endovascular coil therapy (Table 1). The 18 women and 8 men included in the population were aged 44–81 years, with a mean of 62.7 years.

Of the total sample size, 15 of the treated aneurysms had ruptured (presenting with subarachnoid hemorrhage) before the procedure, and 11 were unruptured. Ten subjects demonstrated aneurysms of the anterior communicating artery, 5 aneurysms were located on the middle cerebral artery, 4 aneurysms were on the posterior communicating artery, 3 were located at the basilar artery tip, and 1 each involved the anterior choroidal artery, the petrous internal carotid artery, the superior hypophyseal artery, and the vertebral artery. The mean aneurysm...
height was 5.61 mm (range 2.0–11.8), and the mean maximal width was 5.80 mm (range 3.0–9.9), with mean neck size of 3.91 mm (range 1.9–6.5). The mean dome-to-neck ratio was 1.57 mm (range 0.59–3.39).

Use of Antiplatelets and Anticoagulants before the Procedure

The protocol for the use of antiplatelet and anticoagulant medications was fairly consistent. Aspirin and either clopidogrel or apixaban were provided for patients with unruptured aneurysms (in anticipation if treatment with the Comaneci device was unsuccessful and permanent stent placement was needed to facilitate coiling). Of the 11 patients with unruptured aneurysms, 8 patients were treated with dual antiplatelet therapy. Two received only aspirin monotherapy, and 1 patient did not receive any antiplatelet therapy. Any antiplatelet therapy was discontinued after the procedure after successful use of the Comaneci device. In unruptured cases, heparin was used at the start of microcatheterization in 10 of 11 patients. Among the 15 patients with ruptured aneurysms, 10 received no antiplatelet therapy and 5 received aspirin only. Heparin was administered after the deployment of the first coil in 14 of 15 cases. The 2 patients who required stent placement were given dual antiplatelet therapy in the form of aspirin and clopidogrel.

Fig. 2. Previously coiled, ruptured wide-neck, dysplastic PCOM aneurysm. a, b 3D reconstruction of the right ICA. c Anteroposterior oblique 2D DSA demonstrating the PCOM aneurysm with a daughter sac pointing superiorly and the compacted coil mass. A large PCOM is noted. d, e Unsubtracted image showing the inflated Comaneci after the first framing coil is deployed and after the last coil is deployed into the aneurysm. f DSA final result demonstrating near-complete occlusion of the aneurysm and patent PCOM artery. PCOM, posterior communicating artery; ICA, internal carotid artery.
Procedural Traits
In 24 of 26 procedures, access to intracranial vessels was gained through the femoral artery, and in the other 2, access was via the radial artery. Twenty-eight total Comaneci devices were fully deployed: 2 patients required multiple and varying Comaneci devices. In the first case, 2 Comaneci 17 devices were simultaneously deployed. In the other, a Comaneci 17 and Comaneci Petit were used to achieve the same effect. In the remaining cases, seventeen Comaneci 17 devices, 5 standard Comaneci devices, and 2 Comaneci Petit devices were used. Notably, the Comaneci 17 device is compatible with a 0.017-inch microcatheter and can be delivered through a dual-lumen balloon catheter.

In all of the patients, the physicians were able to deploy and navigate the device to successfully bridge the aneurysmal neck. The mean device exposure time ranged from 8 to 76 min, with a mean of 24 min. Two patients required stent placement. In 1 case, an Atlas stent (Stryker Neurovascular, Salt Lake City, UT, USA) was placed because of the morphology of the aneurysm. In another case, because of a device-related complication, 2 Atlas stents were required. In 2 separate cases, there was evidence of visible clot formation after removal of the devices at the end of the procedure; there were no clinical consequences.

Immediate procedural outcomes showed 16 of 26 cases where complete occlusion was achieved and 4 cases in which near-complete occlusion was achieved (Fig. 2). Five procedures resulted in neck remnant (Fig. 3; see online suppl. Video; for all online suppl. material, see www.karger.com/doi/10.1159/000514371). One displayed residual filling because of a device-related complication. The final angiographic images were reviewed to identify the aneurysm occlusion class – as determined by the Raymond-Roy Occlusion Classification. Of the 26 patients, 16 achieved Class I complete obliteration; 9 had near-complete obliteration or Class II residual neck, and 1 was Class IIIb, in which residual aneurysm with contrast along the aneurysm wall was noted.

Intraprocedural Complications
In 25 of 26 procedures, no complications, retreatments, or thromboembolic events occurred. One patient experienced a technical complication. In this instance, 2 bailout stents were required during the procedure. Two Comaneci 17 devices were placed in the superior and inferior division of the middle cerebral artery. Upon retrieval of the 2 devices, one of the coil loops was attached to the device and continued to pull through the aneurysm. Several attempts were made to recapture the device, but the removal resulted in the movement of the positioned coils out of the aneurysm and into the parent vessel. This event was treated with the placement of 2 Atlas stents with excellent result and no adverse outcome. The final angiographic image demonstrated normal antegrade flow in the affected arteries, but with residual aneurysm filling. On 3-month follow-up, complete occlusion had been achieved. No stroke events occurred.

Discussion
Our results illustrate the successful use of the novel Comaneci device as a temporary adaptable bridging device in the coil-assisted treatment of wide-neck aneu-
Early Experience with Comaneci

The earliest account of the Comaneci device was an animal study by Gupta et al. [10] that examined aneurysm coiling facilitated by the Comaneci device when compared with a compliant HyperGlide balloon (Medtronic, Minneapolis, MN, USA). The authors found similar rates of aneurysm obliteration as well as endothelial damage in both subacute and chronic phases, suggesting a favorable safety profile for the Comaneci device. Lawson et al. [11] then presented the first clinical case report of its successful use in the treatment of cerebral aneurysms. They reported one thromboembolic complication, the precise cause of which was not clear. Multiple reports followed showing promising results with the Comaneci device in the treatment of wide-necked cerebral aneurysms, both unruptured [12] and ruptured [13, 14, 19]. Fisher et al. [12] reported one thromboembolic event in their series of 21 cases, while Sirakov et al. [13] reported 1 case of 29 in which there was severe intraoperative vasospasm and coil protrusion after retraction of the device.

The basic premise of balloon-assisted coiling can be seen in the Comaneci device-assisted coiling strategy; the functionality is similar, but there is no obstruction to the antegrade flow of the parent vessel. This advantage may be significant, as allowing blood flow to continue uninterruptedly lowers the chance of thromboembolic events. It also significantly lowers the risk of vessel rupture, which is a known catastrophic complication of balloon-assisted coiling. A potential limitation of the Comaneci coil assist technique is the inability to obstruct the parent vessel in the event of intraprocedural rupture [13, 16]. Among the various complications associated with endovascular coil embolization, perhaps the most formidable is that of intraprocedural aneurysm rupture. For this reason, some physicians believe balloon remodeling is desirable because the balloon may be inflated, giving physicians more time to control the rupture. Intraprocedural aneurysm rupture while using the Comaneci device would require physicians to control the situation in the same manner as if no balloon was used [20]. Thus, in cases that were high risk for intraprocedural rupture, we delivered the Comaneci 17 device through a Scepter dual-lumen balloon catheter (Microvention, Tustin, CA, USA) in order to have a balloon in the parent vessel proximal to the aneurysm in case a rupture occurred.

The complication of coil entanglement with the struts of the device is rare but possible as seen in one of our cases. The key is to maintain visibility at the neck of the aneurysm, using a working angle that shows the demarcation between the device and the coils. In cases where visualization is not possible, we recommend resheathing or collapsing the device before detachment of coils to ensure no entanglement just as you would deflate a balloon before delivering a coil.

The limitations of this study include its retrospective nature, small number of patients, and lack of long-term follow-up. Furthermore, the absence of a control group treated with either stent-assisted or balloon-assisted coiling techniques limits our ability to extrapolate the effectiveness of Comaneci-assisted coiling in comparison with these current more standard methods of endovascular treatment for WNAs.
Conclusions

Overall, our initial and admittedly limited experience with the Comaneci device demonstrates potential advantages over traditional endovascular treatment strategies. It appears to be a safe and effective alternative to balloon-assisted and stent-assisted coiling techniques. More research and a larger experience are needed to fully understand its role in the endovascular management of wide-necked aneurysms.

Statement of Ethics

On May 26, 2020, Western Institutional Review Board approved a request for a waiver of authorization for use and disclosure of protected health information for this research. This exemption is believed to be exempt under 45 CRF § 46.104(d)(4) because this research involved retrospective review of adult patient charts who received treatment with the Comaneci embolization assist device. The use of the device during procedure was made outside of this research, and data were collected and reported in such a way that human subjects cannot be ascertained directly or through identifiers linked to the subjects. This exemption does apply to multiple sites except for institutions that fall under the jurisdiction of a local IRB; in these cases, further arrangements were made.

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Conflict of Interest Statement

Erez Nossek is a consultant for Rapid Medical. Rishi Gupta is the primary investigator of the TIGER Study. Muhammad Asif Taqi is a consultant for Rapid Medical and a site investigator of the TIGER Study. Philipp Taussky is a consultant for Medtronic, Stryker, and Cerenovus. Howard A. Riina is a consultant for Medtronic.

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