

Long-Term Outcomes of Temporary Stent-Assisted Coil Embolization for the Treatment of Intracranial Aneurysms Using Comaneci Remodeling Device

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BACKGROUND AND OBJECTIVES: Comaneci is temporary embolization assist tool for the treatment of intracranial aneurysms (IAs). The device enables temporarily cover the aneurysm neck with maintaining the blood flow during the procedure. This factor contributes to safe embolization using coils. The study presents the long-term outcomes of temporary stent-assisted coil embolization of IAs using the Comaneci device.

METHODS: The analysis included 100 consecutive patients with incidental compressive and ruptured IAs. Qualification for the treatment with the Comaneci device was a wide-neck aneurysm defined as an IA with a neck width ≥ 4 mm or a dome-to-neck ratio of < 2 . Angiographic follow-ups were conducted 3 and 6 months, 1 year, and 18 months post-procedure, with the modified Raymond-Roy classification.

RESULTS: The patients were treated with: classic Comaneci devices ($n = 35$), Comaneci 17 devices ($n = 60$), and Comaneci Petit devices ($n = 5$). In 97 cases, bridging an aneurysmal neck was successful. At 18 months postprocedure, adequate occlusion (Raymond-Roy 1 + 2) was in 90 patients. Ten patients experienced recanalization of the aneurysm sack (Raymond-Roy 3) and were qualified for a flow diverter stent implantation. The Comaneci device was successfully deployed in all cases.

CONCLUSION: The use of the Comaneci device has a low risk of complications in endovascular treatment of IAs, without procedure-related morbidity and mortality.

KEY WORDS: Aneurysm, Comaneci, Device, Embolization, Hemorrhage, Remodeling

Intracranial aneurysms (IAs) are a leading cause of subarachnoid hemorrhage (SAH), a condition associated with high mortality and morbidity.^{1,2} Most IAs are saccular in shape and originate from branches of the major cerebral vessels forming the Circle of Willis.³ Estimating the risk of rupture is essential for determining the optimal management strategy. Prediction of rupture remains challenging, but it can be influenced by patient-specific factors (e.g., age, sex, smoking, and hypertension) as well as aneurysm-specific factors (e.g., size, location, history of previous SAH, and multiplicity).⁴ Conventional treatment methods include direct surgical clipping or endovascular embolization.⁵ Several studies have suggested that endovascular treatment is

associated with lower rates of symptomatic vasospasm, cerebral infarction, and incomplete occlusion compared with surgical clipping.^{6–8} Craniotomy, on the other hand, may result in postoperative headaches and alterations in the stomatognathic system.⁹ Consequently, endovascular treatment has become the preferred technique for most IAs.^{10,11} In recent years, multiple technologies have been developed to improve the safety and efficacy of endovascular coiling.¹²

Devices such as intracranial stents and balloons have been developed to augment coil embolization, reducing the risk of coil prolapse into the parent artery and providing proximal control through balloon inflation. Another innovation is the use of temporary assist devices, which allow for increased coil packing density and significantly improve occlusion rates.^{13,14} The study presents the Comaneci temporary embolization assist device (Rapid Medical) as a novel tool for the treatment of IAs.¹⁵ Device

ABBREVIATIONS: ACom, anterior communicating artery; DAPT, dual antiplatelet therapy.

has ability to temporarily cover the aneurysm neck, with maintaining the blood flow during procedure.¹⁶

The primary aim of this study was to share our clinical experience and to present the long-term outcomes of temporary stent-assisted coil embolization of IAs performed with the Comaneci remodeling device.

METHODS

Between January 2020 and December 2022, a total of 751 IAs were treated at our institution. Of these, 623 aneurysms (83%) were managed through endovascular techniques, while 128 (17%) underwent microsurgical clipping. Within the endovascular cohort, treatment modalities included coiling (31.2%, n = 194), stent-assisted coiling (29.3%, n = 182), flow diversion (15.5%, n = 97), and Comaneci-assisted coiling (16.0%, n = 100), the latter forming the present study cohort. A retrospective analysis was conducted using data extracted from the hospital information system, which had received prior institutional approval.

Characteristics of Patients and Indications for Treatment

The study included patients with incidental compressive and ruptured aneurysms. The patients were qualified for treatment by neuroradiologists and neurosurgeons with more than 10 years of experience. The decision to use the Comaneci assist device was made by the neuroradiology and neurosurgery team, based on the measurements, location, and morphological characteristics of the IA. Inclusion criteria for the procedure were a wide-neck aneurysm defined as an IA with a neck width ≥ 4 mm or a dome-to-neck ratio < 2 .

Characteristics of the Comaneci Devices

The Comaneci device is a temporary assist stent designed for the coil embolization of IAs. The device consists of 12 (Comaneci and Comaneci petit) or 10 (Comaneci 17) bundles of nitinol wires around a central core wire, with a flexible atraumatic 7-mm tip in the distal portion. The device is available in: Standard Comaneci, length = 32 mm and width up to 4.5 mm; Comaneci Petit, length = 24 mm and a maximum width of 3.5; and Comaneci 17, length = 22 mm and a width of up to 3 mm. The figures show the “deflated” Comaneci device after unsheathing the device from the microcatheter (Figure 1A) and Comaneci after “inflation” in a tube (Figure 1B).

Endovascular Procedures

The Comaneci device was primarily used for wide-neck bifurcation aneurysms, particularly at the middle cerebral artery (MCA), anterior

communicating artery (ACom) and basilar artery where preservation of small branch vessels and avoidance of dual antiplatelet therapy (DAPT) were desirable. Its real-time adjustability allowed continuous parent-vessel perfusion, improved microcatheter stability, and controlled coil deployment. All procedures were performed under general anesthesia. Transfemoral arterial access was obtained; in the next step, Neuro-nMax6F or Fargomax6F guiding catheters were placed in the internal carotid artery (ICA) or the vertebral artery. For Comaneci device detecting, classifying, and planning of the treatment, three-dimensional rotational angiography was performed. To assess the morphology of the sac, neck width, and sizes of the coils, the diagnostic catheter was replaced with a 260-cm long 0.035 guidewire (Terumo Corporation). First, a 0.021// (Comaneci, Comaneci Petit) or a 0.017// microcatheter (Comaneci 17) was navigated into the parent artery, and then, a 0.017// microcatheter was navigated into the aneurysm sack. Microcatheters (Headway17 and Headway21) were put in place with the assistance of a Hybrid 0.014// (Balt) hydrophilic microwire or a Traxcess 0.014// hydrophilic micro guide (Microvention Inc.). Subsequently, 3000 to 5000 units of unfractionated heparin were administered, before expanding the Comaneci device. The first coils were placed into the aneurysm sac before deploying the Comaneci device to ensure that the first part of the coil did not enter the Comaneci mesh. The Comaneci device was expanded until neck bridging was obtained. Afterward, more coils were deployed into the aneurysmal sac until dense packing was achieved without compromising the mandatory maneuver of collapsing the device. The microcatheter was removed from the aneurysmal sac, while the device was expanded (to prevent coil loop protrusion); in the next step, the Comaneci device was resheathed, and both were removed. The puncture site was closed with Angioseal8F/6F or Proglide. The patient was maintained on bed rest for 24 hours and was discharged home the following day.

Medication Management

Seven days before the procedure, patients received clopidogrel (75 mg daily) and acetylsalicylic acid (75 mg daily). Following successful embolization, DAPT was discontinued. In cases where mild coil protrusion was observed, acetylsalicylic acid (75 mg once daily) was continued for 4 weeks. If arterial blood flow slowdown or clot formation occurred, intravenous Integridin (eptifibatid) was administered as a bolus dose, followed by a continuous 12-hour infusion. Blood pressure was increased using vasoactive agents (ephedrine). During embolization, catheters were continuously perfused with heparinized saline (1500 IU/L).

Follow-up

Patients were subsequently followed with scheduled assessments including digital subtraction angiography, the modified Raymond-Roy

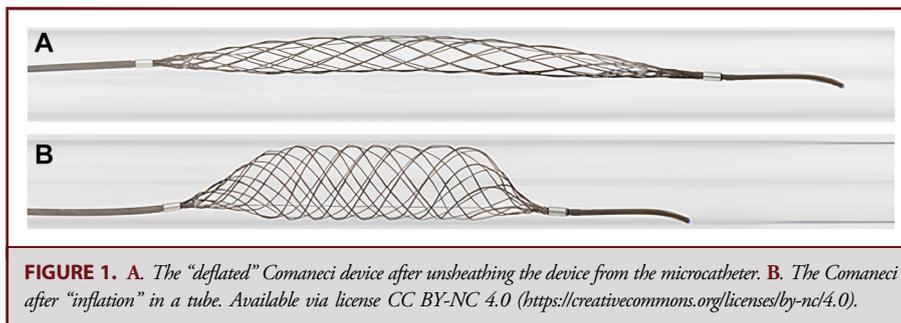


FIGURE 1. A. The “deflated” Comaneci device after unsheathing the device from the microcatheter. B. The Comaneci after “inflation” in a tube. Available via license CC BY-NC 4.0 (<https://creativecommons.org/licenses/by-nc/4.0>).

classification, and the modified Rankin Scale (mRS)—at 3 and 6 months, 1 year, and 18 months postprocedure. Annual clinical follow-up was performed thereafter, either in person or through structured telephone interview. All imaging studies were independently reviewed by 2 senior neurointerventionalists, with discrepancies resolved by consensus.

Ethical Approval

All procedures involving human participants were performed by the ethical standards of the institutional and national research committee and complied 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.

Data Availability

Data available on request from the corresponding author.

RESULTS

One hundred embolization procedures with the Comaneci device were conducted, including 67% female patients and 33% male patients (Table 1). The mean aneurysm height and width were 5.24 and 4.97 mm, respectively, in female patients and 5.71 mm and 5.13 mm in male patients.

In 72% of patients with persistent headache, the IAs were diagnosed during the MRI. Twenty-five percentage of the IAs were found in the ACom with size of 5.21 mm × 4.70 mm (range 2-9 mm for both dimensions). Thirty-four percentage of the IAs were located in the MCA, including 19% in the right MCA (mean height 5.49 mm, range 2.5-14 mm, mean width 5.24 mm, range 2-11 mm) and 15% in the left MCA (mean height 6.04 mm, range 3-14 mm, mean width 5.76 mm, range 6-9.5 mm). For 24% of IAs, the location was the ICA, with 12% of aneurysms found in the left ICA (mean height 5.31 mm, range 3-8 mm, mean width 4.89 mm, range 3-7 mm) and another 12% present in the right ICA (mean height 3.32 mm, range 2.2-8.5 mm, mean width 4.31 mm, range 1.3-3.5 mm). Five percentage of aneurysms, with a mean height of 6.2 mm (range 2-8 mm) and a mean width of 6.32 mm (range 4-7 mm), were located in the basilar artery and 3% with the mean height of 4.23 mm (range 2.6-5.5 mm) and the mean width of 3.3 mm (range 2.4-3.8 mm) in the posterior communicating artery. Another 3% of the IAs, with a main height of 5.33 mm (range 3-7 mm) and a mean width of 5.5 mm (range 3.5-4.5 mm), were located at the origin of the anterior choroidal artery. A total of 4% of the IAs were located on the posterior inferior cerebellar artery, among them 2% were in the right posterior inferior cerebellar artery (mean height 4.55 mm, range 3.8-5.3 mm, mean width 4.85 mm, range 3-6.7 mm) and another 2% in the left posterior inferior cerebellar artery (mean height 5.6 mm, range 4.2-7 mm, mean width 4.1 mm, range 3.7-4.5 mm). Two percentage of the IAs, with a mean height of 6.4 mm (range 5.8-7 mm) and a mean width of

TABLE 1. Characteristics of the Study Patients, Aneurysms, and Devices

Parameter	Number (n = 100)
Sex	
Male	33
Female	67
Age (y)	
20-30	3
31-40	4
41-50	20
51-60	16
61-70	28
71-80	24
81-90	5
Size of aneurysm	
Small ^a	43
Medium ^a	54
Large ^a	3
Location	
LMCA	15
RMCA	19
ACom	25
PCoA	3
LICA	12
RICA	11
RPICA	2
LPICA	2
BA	5
ACA	1
OA	2
AChoA	3
Device	
Comaneci 17	60
Comaneci	35
Comaneci Petit	5
Remodeling	100

ACA, anterior cerebral artery; AChoA, anterior choroidal artery; ACom, anterior communicating artery; BA, basilar artery; LICA, left internal carotid artery; LMCA, left middle cerebral artery; LPICA, left posterior inferior cerebellar artery; OA, ophthalmic

artery; PCoA, posterior communicating artery; RICA, right internal carotid artery; RMCA, right middle cerebral artery; RPICA, right posterior inferior cerebellar artery.

^aSmall <5 mm, medium 5-10 mm, large 10-25 mm, giant >25 mm; according to the Natural Course of Unruptured Cerebral Aneurysms in a Japanese Cohort study.

4.35 mm (range 4-4.7 mm), were found in the ophthalmic artery, and 1 aneurysm (1%, 6 mm in height and 6 mm in width) was located in the anterior cerebral artery.

A total of 100 Comaneci devices were used throughout the study with 97% successful rate. The device was insufficient to provide a stable coil position inside the aneurysmal sack in 3 patients. The follow-up was done with angio-MRI or digital subtraction angiography if the results were not diagnostic. The rate of adequate occlusion (Raymond-Roy 1 + 2) at 18 months postprocedure was 90%. Seventy-six patients presented a complete aneurysm occlusion (Raymond-Roy 1); 14 patients had aneurysm neck remnant that did not require any further endovascular or microsurgical intervention (Raymond-Roy 2). Ten patients experienced recanalization of the aneurysm sack (Raymond-Roy 3) and were qualified for a flow diverter stent implantation (Table 2).

All patients had mRS of 0 or 1 at 3 months postprocedure (Table 3). No intraprocedural and vasospasm or parent artery wall dissection was observed.

DISCUSSION

Key Results

The study presents 97% success rate in bridging aneurysmal neck in European patients. In 3 patients with SAH, intraprocedural thrombus formation occurred in the (MCA) at the site of the device. Although the Comaneci was deployed, aneurysm neck protection was not achieved due to thrombus development. The device was withdrawn, intravenous eptifibatid was administered, and stent implantation was performed. These cases were considered treatment failures of the device. Trotman-Lucas and Gibson¹⁷ and Margetis and Sánchez-Manso¹⁸ indicate MCA as the most common pathologically affected blood vessel overall because of embryological and genetic factors such as metabolic demands, vasculogenesis and angiogenesis, accessory or duplicated vessels, and structural anomalies.^{17,18}

The primary complication was a coil protrusion. According to Mascitelli et al¹⁹ and Müller et al,²⁰ endovascular coiling,

especially for wide-necked aneurysms, is associated with an increased risk of coil mass protrusion into the parent vessel. In our study, protrusion into the parent vessel lumen occurred in the 6 cases. In 2 of these cases, the procedure was aborted due to unfavorable aneurysm morphology leading to coil instability and protrusion; the coils were removed, and the patients underwent microsurgical clipping.

In 4 patients, coil protrusion occurred but was not clinically significant. The procedures were completed successfully, and DAPT was continued postoperatively for 3 months. That implies a risk of coil protrusion even in aneurysms with narrow necks. To prevent or minimize the “push back” effect, the jailing microcatheter technique is crucial, whenever a difficult angulation of the parent vessel to the aneurysm sac is observed.²¹ In some cases, the aneurysmal neck is not clearly visible under fluoroscopy, or the operator is unsure whether the coil loop entered the mesh of the device after it has been collapsed. Under such circumstances, it is recommended to slide the microcatheter over the Comaneci device (resheathing) to check for any potential resistance.²² Three patients were discharged with mild symptoms of hemiparesis. The clinical condition of these patients significantly improved to 1 (mRS) within 6 months. No vasospasms or treatment-related bleeding or deaths were reported (Table 4).

Limitations of the Study

This study has several limitations. Its observational design from a single institution may introduce selection bias, especially regarding favorable aneurysm anatomy. The 18-month follow-up might miss late recanalization. The lack of a control group limits comparisons with other treatments such as surgical clipping or traditional flow diverters. In addition, the retrospective nature restricts multivariable analysis of prognostic factors. Longer follow-up is needed to assess long-term safety and efficacy.

Interpretation

Presented findings imply that the Comaneci device is an effective and safe option in patients with IAs. Previously published data, in a systematic review and meta-analysis involving 255 patients, Sun et al²³ estimated the overall incidence of periprocedural complications at 10.9%, with the rate of complete or adequate occlusion reaching up to 98%. Taqi et al²⁴ reported no complications, retreatments, or thromboembolic events in

TABLE 2. Raymond-Roy Scores Throughout the Study

Raymond-Roy score	Postprocedure (n = 100)	6 mo (n = 100)	12 mo (n = 100)	18 mo (n = 100)
Raymond-Roy 1	84	82	79	76
Raymond-Roy 2	14	11	12	14
Raymond-Roy 3	2	7	9	10

TABLE 3. Modified Rankin Scores Throughout the Study

Modified Rankin score	0-1 at discharge (n = 100)	2 at discharge (n = 100)	0-1 at 3 mo (n = 100)
No. of patients	97	3	100

patients treated with the Comaneci device. One patient experienced a technical issue with coil loops attached to the device and continued to pull through the aneurysm. Sirakov et al¹⁶ presented a series of 118 ruptured aneurysms successfully treated with the Comaneci device, with periprocedural thromboembolic complications occurring in 7/118 patients, severe vasospasm of the parent artery after manipulation with the device in 5/118 and morbidity rate of 2.54%. Complete aneurysmal obliteration was achieved in 81/112 patients, with a 14.28% total recanalization rate.¹⁶

Some authors analyze the safety and efficacy of the Comaneci device compare with other available treatment options in patients with IAs. According to Gottmann et al²⁵ and Lim et al,²⁶ the safety of the procedure is similar to balloon remodeling or permanent stent-assisted coiling but is associated with lesser demand for antiplatelet therapy and could be safely applied in patients with ruptured IAs.²⁴⁻²⁶ It is worthy to notice that device does not pose a risk compare to the balloon treatment.²⁷ The balloon technique may increase the risk of thromboembolic complications during the procedure. In a series of 1088 patients examined by Pierot et al,^{28,29} the thromboembolic events occurred in 113 (10.4%), and 34 (3.1%) intraoperative ruptures were reported. Poor clinical outcome (Rankin Scale score of 3-6) was reported in 29 of 113 participants (25.7%) with thromboembolic events and in 11 of 34 participants (32.4%) with intraoperative rupture.^{28,29} In our center, balloon-assisted coiling is reserved for a limited subset of aneurysms with unfavorable neck geometry. The Comaneci device has replaced balloons in wide-necked aneurysms cause of continuous blood flow during coil deployment, eliminating the repetition of inflation–deflation. This reduces flow arrest risks, improves operator confidence, and enhances procedural ease,

especially in tortuous vessels. Its adjustable mesh and real-time control offer better microcatheter stability and decrease coil protrusion or catheter kickback. Overall, these features enable smoother procedures, less intraoperative stress, and maintain optimal hemodynamic safety.

Another important consideration is the device's compatibility and ease of use with standard microcatheters. Based on our experience, the Comaneci device offers superior flexibility, making it easier and more comfortable to navigate. This observation is supported by several authors, including Sirakov et al,¹⁶ Lawson et al,³⁰ Fischer et al,³¹ and Cottier et al,³² who emphasize that Comaneci provides the same benefits as balloon remodeling without the associated risk of parent artery occlusion—thereby reducing procedural time pressure. Wessels et al^{15,33} describe Comaneci as a flexible device that enables gentle and safe navigation, eliminating the need for inflation/deflation maneuvers required in balloon-assisted coiling. Molina-Nuevo et al¹⁵ further highlight that the flexible tip significantly enhances navigability. The device has shown particular efficacy in aneurysms located at the MCA bifurcation, basilar tip, and ACom complex, where balloon-assisted techniques are often limited by vessel tortuosity or unstable microcatheter positioning, as noted by Aoki et al.³⁴ Its ability to preserve patency in small-caliber branch vessels offers a distinct procedural advantage in bifurcated anatomy over temporary balloon remodeling.

Summary

Our findings suggest that the use of the Comaneci device is associated with a low risk of complications and successful endovascular treatment of IAs, without procedure-related morbidity and mortality, in up to 97% of the cases. Its flexibility, hemodynamic safety, and procedural efficiency have made it a preferred tool in selected cases at our institution.

Similar findings were presented by Tagi et al²⁴ who show that Comaneci is reliable and safely support coil remodeling of IAs. Notably, the rate of coil protrusion may depend on the operator's experience and skills and on the aneurysm's shape. This issue was also discussed by Lorenzo et al³⁵ and Changya et al.^{35,36} Doshi et al³⁷ clearly indicate that operators experience and expertise are necessary for deploying coils. The good practice to prevent coil protrusion may be resheathing the device by operator, before deploying each coil and reposition each coil attached to the mesh. It should be emphasized that the Comaneci have some limitations. The primary limitation of this device is its inapplicability in the treatment of giant aneurysms (>25 mm), where a flow diverter would likely be more appropriate. In such cases, microsurgical clipping remains the treatment of choice and

TABLE 4. Intraprocedural Complications

Complication	Number (n = 100)
Coil protrusion into parent artery due to wide neck aneurysm	6
Thromboembolic event	3
Coil loop entrapped in mesh	0
Vasospasm	0
Parent artery dissection	0
Device malfunction	0

has demonstrated effectiveness, as reported by Campos et al.³⁸ Management of ruptured aneurysms also presents significant challenges. The Comaneci-assisted technique offers a versatile, flow-preserving alternative for complex aneurysms that would otherwise necessitate permanent stent implantation or high-risk balloon remodeling. However, sharp vessel angulation may limit the efficacy of temporary bridging, occasionally requiring conversion to permanent stenting. Finally, both the learning curve and anatomic constraints—particularly giant aneurysms and unfavorable vessel angulation—constitute practical limitations of this technique.

CONCLUSION

The use of the Comaneci device is associated with a low risk of complications, allowing for successful endovascular treatment of IAs, without procedure-related morbidity and mortality. Ongoing prospective comparisons and multicenter analyses will be essential to further define its role and long-term performance relative to established adjunctive methods.

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