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Case series

Comaneci-assisted embolization of wide-necked aneurysms: results from the SUCCESS postmarket US study

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ABSTRACT

Background Wide-necked intracranial aneurysms present unique challenges for endovascular treatment. The Comaneci device is a novel temporary bridging device designed to assist coil embolization without parent vessel occlusion.

Methods The SUccess in Comaneci-assist Coils Embolization Surveillance Study (SUCCESS) was a multicenter, prospective, postmarket surveillance study conducted at 17 US centers. Ninety consecutive patients with wide-necked intracranial aneurysms were treated with Comaneci-assisted coiling. The primary effectiveness endpoint was successful aneurysm occlusion (Raymond-Roy class I/II) at procedure end. Primary safety endpoints included periprocedural events within 24 hours and clinical outcomes at discharge and 30 days.

Results Of 90 enrolled patients (mean age 63 years, 63% female), 32 (36%) presented with ruptured aneurysms. Most common locations were anterior communicating (33%), internal carotid (20%), and posterior communicating arteries (19%). Successful occlusion was achieved in 85.6% of cases at procedure end and 94.7% at 6 months. Good clinical outcome (modified Rankin Scale (mRS) 0–2) was maintained from baseline (73%) through 30 days (81%) and 6 months (83%). Thromboembolic events occurred in 5.5% of cases, all asymptomatic. Device-related complications were minimal, with coil entanglement in 0.3% of deployed coils and no instances of deployment/retrieval failure. All-cause mortality was 4.4%, confined to the ruptured aneurysm cohort.

Conclusions The SUCCESS study demonstrates high rates of successful aneurysm occlusion with Comaneci-assisted coiling, with occlusion rates persisting through 6 month follow-up. The safety profile was favorable, with low rates of thromboembolic events compared with other assist techniques. These results support the use of the Comaneci device for wide-necked aneurysm treatment in both ruptured and unruptured settings.

Trial registration number NCT04518670.

INTRODUCTION

Intracranial aneurysms affect approximately 2% of the general population.[1 2] Wide-necked aneurysms, defined as those with a neck width ≥4 mm or dome-to-neck ratio <2, present particular technical challenges for endovascular treatment due to the risk of coil herniation into the parent vessel. Although endovascular techniques for aneurysm treatment have progressed significantly. Wide-necked aneurysms remained challenging to treat with standard coiling alone. Balloon-assisted coiling emerged as an important technique for these complex lesions, with studies demonstrating improved immediate occlusion rates compared with conventional coiling.[3–5] Despite its advantages, balloon remodeling requires temporary parent vessel occlusion during coil deployment and carries risks of thromboembolic complications.

Stent-assisted coiling emerged as another alternative technique for wide-necked aneurysms, with several studies showing favorable initial occlusion rates. However, recent evidence indicates significant recurrence rates ranging from 7.7% to 15.5% depending on aneurysm characteristics.[6–10] Retreatment rates after stent-assisted coiling have been reported between 4.6% and 6.4% in recent literature.[8–10] Additionally, stent placement necessitates dual antiplatelet therapy, which may be contraindicated in patients with ruptured aneurysms or those requiring urgent surgical interventions.[11] Extended use of dual antiplatelets have also been shown to have significant rates of nuisance bleeding complications.[12]

The Comaneci device, as shown in figure 1 (Rapid Medical, Israel), was developed as an innovative alternative approach, providing temporary bridging support during coiling without interrupting blood flow.[13 14] Unlike balloons or stents, the Comaneci is fully retrievable after coil deployment and does not require long-term dual antiplatelet therapy.[14–16] The device received Food and Drug Administration (FDA) approval in 2019,

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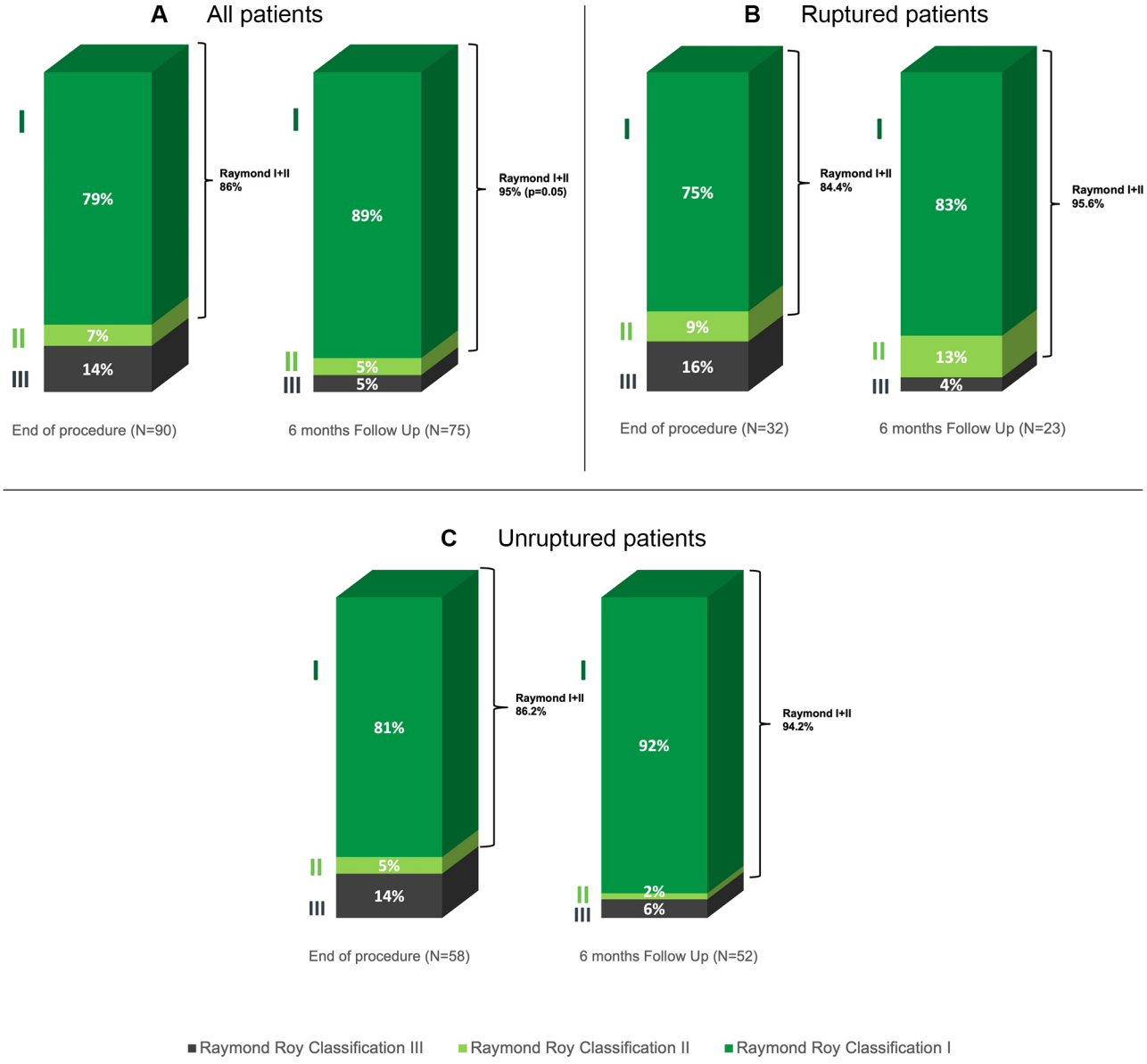

Figure 1 Successful intracranial aneurysm occlusion (measured by Raymond Roy Classification I or II). (A) All, (B) Ruptured cases, (C) Unruptured cases.

representing the first temporary neck-bridging device available in the US market.

The SUCCESS study represents the first large-scale evaluation of the Comaneci device in US clinical practice since FDA approval. This prospective, multicenter study was designed to assess real-world safety and effectiveness in both ruptured and unruptured wide-necked aneurysms.

METHODS

Study design

The SUccess in Comaneci-assist Coils Embolization Surveillance Study (SUCCESS) was a prospective, single-arm, multicenter postmarket surveillance study conducted at 17 US centers between November 2020 and October 2023. The study was registered on ClinicalTrials.gov (NCT04518670) and approved by institutional review boards at all participating centers.

The sponsor, Rapid Medical, and its contracted Contract Research Organization (Vastrax, Inc Philadelphia, PA, USA) were responsible for logistical operations, data management, and monitoring of the trial. The study protocol was approved by the institutional review board or ethics committee at each participating site.

The study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies.[17]

Patient population and procedure

Eligible patients had documented intracranial aneurysms suitable for coil embolization with neck width ≥4 mm or dome-to-neck ratio <2. Both ruptured and unruptured aneurysms were included. The only exclusion criterion was known hypersensitivity to nickel-titanium. Procedures were performed under standard institutional protocols for anticoagulation and antiplatelet therapy.

Study endpoints

The primary effectiveness endpoint was successful aneurysm occlusion (Raymond-Roy class I or II) at the end of the

Table 1 Demographics

N	90
Age, Mean (Range)	63 (30–83) years
Gender, n (%)	57 Female (63), 33 Male (37)
Race, n (%)	American Indian or Alaska Native - 1 (1.1)
	Asian - 3 (3.3)
	Black or African American - 15 (16.6)
	Native Hawaiian or Other Pacific Islander - 0
	White - 66 (73.3)
	Other - 5 (5.5)
Aneurysm type (Ruptured/ Unruptured), n (%)	Ruptured - 32/90 (35.5)
	Unruptured- 58/90 (64.4)
Aneurysm location, n (%)	ACA - 3 (3.3)
	ACOMM - 30 (33.3)
	Basilar - 4 (4.4)
	ICA - 18 (20.0)
	MCA (M2) - 14 (15.5)
	Vertebral - 1 (1.1)
	PCOMM - 17 (18.8)
	PICA - 2 (2.2)
	SCA - 1 (1.1)

procedure. Safety endpoints included periprocedural events within 24 hours, all adverse events through 30 days, and functional outcomes (modified Rankin Scale (mRS)) at discharge and 30 days. Additional endpoints included occlusion stability at 6 months and clinical outcomes measured by mRS shifts.

Data collection and analysis

Independent core lab (Brainstorme, Inc. UCLA) adjudication was performed for all angiographic outcomes. Clinical events were adjudicated by an independent Data Safety Monitoring Board consisting of a neurosurgeon, neuro-interventionalist, and a biostatistician. Statistical analysis was primarily descriptive, performed by Biomedical Statistical Consulting LLC,Philadelphia, PA, USA, using SAS/STAT.

RESULTS

Patient and aneurysm characteristics

Ninety consecutive patients were enrolled (mean age 63 years, range 30–83; 63% female). Thirty-two patients (36%) presented with ruptured aneurysms. The most common aneurysm locations were anterior communicating artery (33%), internal carotid artery (20%), posterior communicating artery (19%), and middle cerebral artery (16), table 1.

Procedural outcomes

Initial technical success with device deployment was achieved in all cases. Mean procedure duration was 98.3 minutes (min). The Comaneci device was inflated for an average of 16.1 min per case, with a mean of 4.3 coils deployed per aneurysm (table 2).

Effectiveness

The primary effectiveness endpoint was met with successful occlusion (Raymond-Roy I/II) achieved in 85.6% of cases immediately post-procedure. Complete occlusion (Raymond-Roy I) was achieved in 78.9%. At 6 month follow-up, successful occlusion improved to 94.7%, with complete occlusion in 89.3%. Results were comparable between ruptured (95.6%) and unruptured (94.2%) cohorts figure 1A–C, table 3.

It is worth noting that retreatment was required in only one case (1.1%). This case included a ruptured aneurysm treatment. Raymond Roy at the end of the procedure was II and stable at 3 months follow-up. On 3 month follow-up angiogram, the patient was noted to have filling of the previously treated right ICA aneurysm. Given the history of previous ruptures and treatment of the same aneurysm, the patient underwent additional stent-assisted coil embolization.

Examples of a ruptured and an unruptured wide neck aneurysm both treated successfully (Raymond- Ray I) with the Comaneci, stable at 6 months follow-up, are presented in figure 2.

Safety

The 30-day mortality rate was 4.4% (4/90), all in the ruptured aneurysm cohort. Thromboembolic events occurred in 5.5% (5/90) of cases, non-symptomatic. Device-specific complications were rare, with one incidence of coil entanglement (0.3%, 1/386 of deployed coils), which was resolved during the procedure (table 4). It is noteworthy that intraoperative complication rates were not correlated with the operators' experiences based on the number of similar procedures and the years of experience of the operators.

Clinical outcomes

Good clinical outcome (mRS 0–2) rates improved from baseline (73%) through 30 days (81%) and 6 months (83%). This improvement was not statistically significant ($p=0.2$ at 30 days and $p=0.1$ at 6 months), in the overall cohort and the elective, unruptured subgroup. However, the good clinical outcome improvement at 6 months in the ruptured cohort was statistically significant (73.3% vs 46.8%, $p=0.03$), figure 3A–C.

DISCUSSION

The SUCCESS study represents the largest prospective evaluation of the Comaneci device in US clinical practice, demonstrating high rates of technical and clinical success in treating wide-necked aneurysms. The immediate occlusion rate of 85.6% compares favorably with historical results for balloon-assisted coiling, while the improvement to 94.7% at 6 months suggests durability of treatment.

Particularly noteworthy is the low rate of thromboembolic complications (5.5%) compared with reported rates with other techniques. Recent systematic reviews and meta-analyses report higher thromboembolic events with alternative modalities: coiling alone (13.6%),[3 4] balloon-assisted coiling (9.8%),[3 4 18] stent alone (16.3%),[19] and stent-assisted coiling (5.4).[20–23] These prior studies have heterogeneous definitions and methods of detection, with some relying solely on angiography or clinical adjudication and others incorporating MRI/diffusion-weighted imaging (DWI), whereas in our study all thromboembolic events were independently reviewed by the core lab and adjudicated by the Data Safety Monitoring Board (DSMB). Our observed rate of thromboembolic events with Comaneci (5.5%) positions this technique favorably in the spectrum of available options. Importantly, none of the thromboembolic events in our study were symptomatic, in contrast to symptomatic rates of 2.2%–10% reported with stent-assisted coiling and stent only.[19 22 24]

The successful and durable aneurysm occlusion was accompanied by a sustainable improvement in good clinical outcome as measured by mRS 30 days and 6 months post-treatment. The

Table 2 Intraoperative data and procedural characteristics

Variable	Group	N	Mean (SD)	Med	Min	Sum
Time that Comaneci device was inflated (minutes)	All	90	16.1 (12.7)	15 (7–21)	0.78	
	Ruptured	32	16.4 (14.4)	16 (6.5–21.5)	0.78	
	Unruptured	58	15.9 (11.8)	14.5 (8-21)	0.56	
Total number of coils used	All	90	4.3 (2.4)	4 (3-5)	1,13	386
	Ruptured	32	4.4 (2.3)	4 (3–5.5)	1,13	142
	Unruptured	58	4.2 (2.4)	4 (3-5)	1,12	244
Procedure duration (minutes)	All	90	98.3 (45.2)	91.5 (69-105)	43, 283	
	Ruptured	32	92.3 (45.7)	86.5 (62.5–100.5)	43, 247	
	Unruptured	58	101.6 (45)	92.5 (71-105)	50, 283	

			N	n (%)
Comaneci device used	Comaneci	All	90	25 (27.8)
		Ruptured	32	8 (25)
		Unruptured	58	17 (29.3)
	Comaneci 17	All	90	56 (62.2)
		Ruptured	32	20 (62.5)
		Unruptured	58	36 (62.1)
	Comaneci Petit	All	90	9 (10.0)
		Ruptured	32	4 (12.5)
		Unruptured	58	5 (8.6)
Sedation type used	General	All	90	89 (98.9)
		Ruptured	32	32 (100.0)
		Unruptured	58	57 (98.3)
	Local	All	90	1 (1.1)
		Ruptured	32	0 (0.0)
		Unruptured	58	1 (1.7)

fact that the improvement in clinical outcome was statistically significant in the patients admitted with ruptured aneurysms further supports the conclusion that Comaneci is safe and effective in the acute ruptured cases where the treatment is performed promptly to avoid any further rupture.

The absence of parent vessel occlusion during Comaneci-assisted coiling likely contributes to its favorable safety profile. Balloon-assisted techniques require intermittent flow arrest, which has been associated with increased thromboembolic risk, particularly during longer inflation periods. The Comaneci's adjustable mesh design allows maintained perfusion during coil deployment while still providing effective neck coverage. This offers an advantage in patients with tenuous collateral circulation or those intolerant to temporary occlusion.

Table 3 Angiographic outcomes

	All	Ruptured	Unruptured
Immediate aneurysm occlusion- End of procedure	n=90	n=32	n=58
Raymond-Roy Classification I n (%)	71 (79)	24 (75)	47 (81)
Raymond-Roy Classification II n (%)	6 (7)	3 (9)	3 (5)
Raymond-Roy Classification III n (%)	13 (14)	5 (16)	8 (14)
Angiographic outcomes at 6 months follow-up	n=75	n=23	n=52
Raymond-Roy Classification I n (%)	67 (89)	19 (83)	48 (92)
Raymond-Roy Classification II n (%)	4 (5)	3 (13)	1 (2)
Raymond-Roy Classification III n (%)	4 (5)	1 (4)	3 (6)

Device-related complication rates were also low. In our cohort, coil entanglement occurred in only 0.3% of deployed coils, and no instances of device deployment or retrieval failure

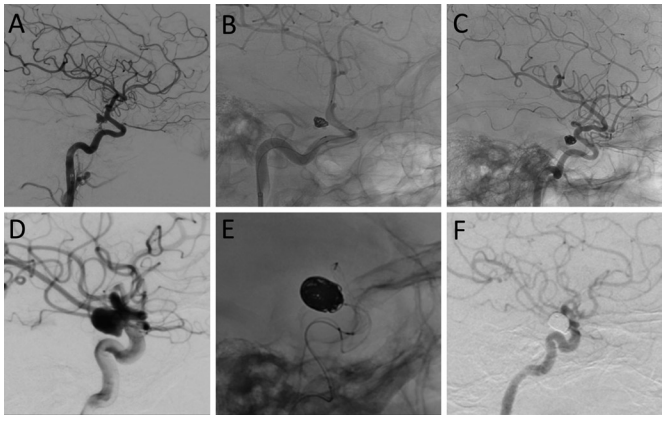

Figure 2 (A) (A–C) Case 1: Treatment of a wide-neck ruptured internal carotid artery (ICA) aneurysm (dome-to-neck ratio: 1.75; neck width: 3 mm) using the Comaneci device. (A) Pre-treatment CT angiography. (B) Post-treatment imaging. (C) Six-month follow-up CT angiography. (D–F) Case 2: Treatment of a wide-neck unruptured posterior communicating artery (PCOM) aneurysm (dome-to-neck ratio: 2.17; neck width: 5.49 mm) using the Comaneci device. (D) Pre-treatment CT angiography. (E) Post-treatment imaging.(F) Six-month follow-up CT angiography.

Table 4 Safety

	All (n=90)	Ruptured (n=32)	Unruptured (n=58)
Thromboembolic events n (%)	5 (5.5)	3 (9.4)	2 (3.4)
Symptomatic thromboembolic events n (%)	0	0	0
Mortality n (%)	4 (4.4)	4 (12.5)	0
Coil entanglement/total coils n (%)	1/356 (0.3)	0/134 (0)	1/222 (0.5)
Vessel perforation or dissection* n (%)	2 (2.2)	1 (3.1)	1 (1.7)
Intracranial aneurysm rupture* n (%)	1 (1.1)	0	1 (1.7)
Hemorrhage* n (%)	5 (5.5)	4 (12.5)	1 (1.7)

*Unrelated to Comaneci.

were observed. This compares favorably to balloon-assisted coiling, where complication rates of 11.5–13.3% have been reported, including both thromboembolism and iatrogenic rupture.[25 26] Similarly, stent-assisted coiling carries thromboembolic and hemorrhagic risks that have been estimated at about 9.5%.[8 9]

Coil entanglement, though infrequent, represents a significant procedural challenge with potential implications for both parent vessel safety and aneurysm durability. In our case, entanglement occurred after deflation of the Comaneci device, resulting in coil protrusion into the ICA; bailout stenting from the M1 to ICA secured the construct, while a non-flow-limiting loop remained

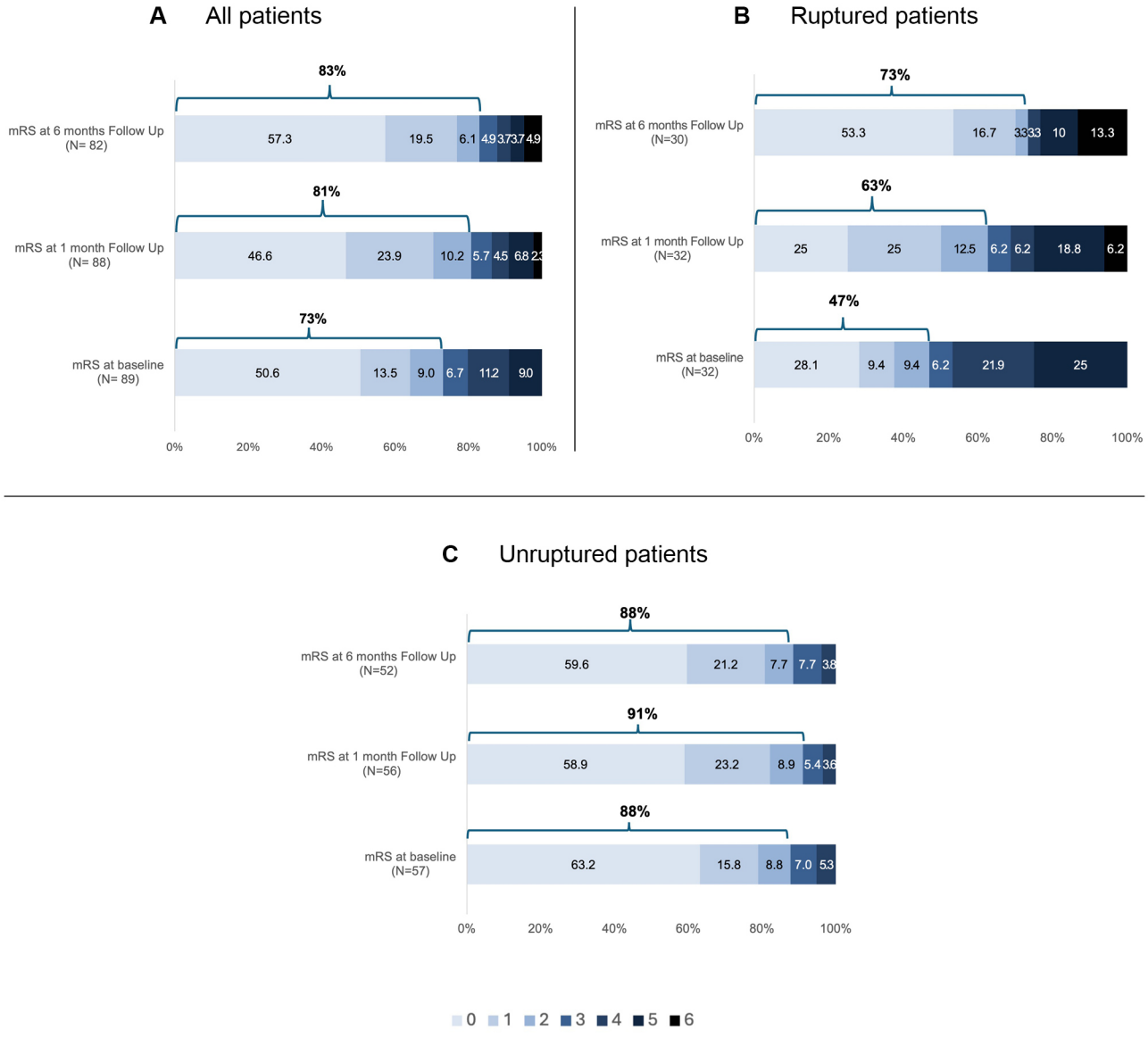

Figure 3 Functional status at baseline, 1 month and 6 months assessed using the modified Rankin Scale (mRS). (A) all, (B) Ruptured (C) Unruptured.

in the A1. The patient was neurologically intact at 30-day follow-up (Raymond-Roy IIIA). Preventive strategies include meticulous device sizing, stable microcatheter positioning, and avoidance of nano coils across the neck. Bailout options include stent-assisted rescue, balloon remodeling, or retrieval, whereas stable non-flow-limiting loops may be observed under long-term antiplatelet therapy.[27 28]

The unsuccessful occlusion and retreatment rates observed at 6 months in our study were also promising. Unsuccessful occlusion rates (Raymond Roy III) following endovascular treatment of wide-necked aneurysms have been reported as high as 19.9% for conventional coiling,[29] 9.9% for balloon-assisted coiling,[28] and 4–5% for stent-assisted coiling.[21 22 30] Our observed unsuccessful occlusion rate of 5.3% compares favorably with these historical benchmarks. Similarly, the retreatment rate in our cohort was 1.1% (1/90), lower than reported rates of 4.6–11.9% with other endovascular techniques.[8–10]

Recent studies on the Comaneci device have reported similar findings. Sirakov *et al*,[15] demonstrated complete or near-complete aneurysm occlusion in 83.0% of cases at 6 month follow-up. The authors also found thromboembolic complication rates of 5.93%, very close to our observed 5.5% rate. This growing body of literature supports the safety and effectiveness profile we observed in the SUCCESS study.

Interestingly, several off-label uses of the Comaneci device have been reported, most commonly as an alternative to balloon angioplasty. These include augmentation of vessel wall apposition after flow-diverter deployment and treatment of refractory cerebral vasospasm.[31 32]

The similar effectiveness outcomes between ruptured and unruptured cohorts suggest the device is equally useful in both settings. The mortality rate of 12.5% in the ruptured cohort aligns with expected outcomes for this high-risk population.

Study limitations include the single-arm design and 6 month follow-up period. Longer-term follow-up would be valuable to assess durability of treatment. Additionally, while the study included multiple centers, operator experience with the device was variable, although complication rates were not correlated with the operators' experience. Future studies comparing Comaneci directly to balloon-assisted or stent-assisted coiling in a randomized fashion would provide stronger comparative evidence.

CONCLUSION

The SUCCESS study demonstrates that Comaneci-assisted coiling provides safe and effective treatment of wide-necked intracranial aneurysms in real-world practice. The high rate of successful occlusion, favorable safety profile, and good clinical outcomes support its role as an alternative to balloon assistance for complex aneurysm treatment.

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