

# Challenging the limits of angioplasty: Comaneci device for distal vasospasm following subarachnoid hemorrhage

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## Abstract

**Introduction:** Aneurysmal subarachnoid hemorrhage (aSAH) is often complicated by delayed cerebral vasospasm (DCV), a major cause of morbidity and mortality. Balloon angioplasty is standard for refractory cases but carries a high risk in distal vessels. This study reports preliminary single-center experience with the Comaneci device for DCV, emphasizing distal segments beyond the circle of Willis, where evidence remains limited.

**Methods:** We retrospectively analyzed patients with aSAH and symptomatic DCV refractory to medical therapy treated with Comaneci-assisted angioplasty (CAA). Demographic, procedural, clinical, and angiographic data were collected from electronic records. Angiographic response was graded using a vasospasm severity scale.

**Results:** CAA was performed in 94 vessels across 14 patients (median age 63 years; 85.7% female). Severe-to-critical vasospasm was present in 88.6%. Most interventions involved the anterior circulation (79.1%), with distal segments (M2 and A2–A4) comprising 54.1%. The M2 segment was most frequently treated (36.4%). Patients underwent a median of three interventions (range 2–6). Angioplasty resulted in significant resolution of vasospasm in 92.7% of vessels, with retreatment required in 8.3%. At 6 months, a favorable outcome (mRS 0–2) was observed in 51.5% of patients, while 90-day mortality was 21.4%. No vessel perforations or long-term complications occurred; one transient occlusion was successfully managed with aspiration.

**Conclusions:** CAA appears feasible and safe for DCV, particularly in the distal vasculature where balloon angioplasty is rarely used. These findings suggest the device may provide a valuable alternative to conventional therapy. Larger prospective studies are required to confirm safety, efficacy, and long-term clinical impact.

## Keywords

Distal vessel, aneurysm, subarachnoid hemorrhage, vasospasm, angioplasty

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## Introduction

Aneurysmal subarachnoid hemorrhage remains a critical neurological emergency with significant morbidity and mortality, affecting a substantial proportion of patients in the acute phase or within the first few weeks following aneurysm rupture. Despite effective initial management, delayed cerebral vasospasm (DCV) remains the leading cause of death and disability in this population, occurring in ~70% of patients with aneurysmal subarachnoid hemorrhage (aSAH), and only 20%–30% will present with clinical changes, including ischemic stroke or death if not promptly and effectively managed.<sup>1</sup> Calcium channel blockers, particularly oral nimodipine, are currently the only approved prophylactic treatments. However, in cases refractory to medical therapy, endovascular intervention is often required.<sup>2</sup> Among endovascular options, intra-arterial (IA) vasodilator therapy and balloon angioplasty remain the most utilized techniques. Nevertheless, there is considerable variability and a lack of consensus regarding their indications, safety, and efficacy. Balloon angioplasty, while

effective, carries procedural risks, especially in distal or tortuous vessels where mechanical dilation may result in arterial injury.<sup>3</sup> In recent years, there has been growing interest in mechanical endovascular techniques using stent retrievers to achieve consistent and safe vessel dilation. Although the radial force of the available stentriever is much lower than that of balloons, it is assumed that they may be of use in treating DCV, and recently, other groups have published their experience in this issue.<sup>4,5</sup> The Comaneci device (Rapid Medical, Yokneam, Israel) is a compliant, manually expandable mesh

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initially approved as a temporary bridging device for wide-neck aneurysm coiling.<sup>6,7</sup> Its off-label use for refractory intracranial vasospasm has been explored in preliminary reports, given its unique ability to apply controlled, incremental radial force while preserving antegrade flow. Notably, the device is particularly advantageous in distal vessel segments, where balloon angioplasty is typically avoided due to the elevated risk of rupture or dissection. In this context, we present our single-center experience using the Comaneci device for endovascular treatment of symptomatic, medically refractory vasospasm following aSAH (including distal segments), highlighting its potential role in improving outcomes where conventional techniques may fall short.

## Methods

Patients were retrospectively analyzed in a single-center observational study between August 2019 to November 2024, conducted at a tertiary academic hospital. Device usage, procedural details, and outcome adjudication were determined based on a standardized diagnostic and treatment protocol. Inclusion required angiographically confirmed vasospasm in both the anterior and posterior circulation that was refractory to medical therapy, including intravenous hypertensive management and IA vasodilators. Baseline demographic data, clinical presentation, radiologic features, procedural specifics, and clinical outcomes were systematically documented according to predefined criteria.

## Population

Institutional Review Board (IRB) approval was obtained prior to study initiation. Due to its retrospective design, informed consent was waived. Patients undergoing mechanical angioplasty using the Comaneci device for refractory intracranial vasospasm were retrospectively identified from our center database. Not all treated segments were associated with overt clinical manifestations, as some patients did not present with focal neurological deficits. In several cases, treatment was initiated due to lack of improvement in the level of consciousness, unexplained elevation of intracranial pressure, or the appearance of new ischemic lesions on interval imaging, rather than clear focal deficits. Eligible patients exhibited vasospasm secondary to aSAH, confirmed angiographically, and refractory to optimal medical or IA vasodilatory treatments. The decision to perform endovascular treatment was determined solely by the treating neuro-interventionalist. Technical aspects, including the selection of microwires, microcatheters, guide catheters, and the specific Comaneci device variant (Comaneci-17, Comaneci-21, or Comaneci Petit), remained at the operator's discretion based on angiographic vessel measurements. Procedures were performed under live fluoroscopy, deploying the device through gradual, incremental expansion, confirmed with contrast injections. The device remained fully expanded for ~120 seconds before deflation and repositioning, generally progressing from distal to proximal vessels. Baseline clinical and radiological data, procedural specifics, and outcomes were systematically collected. Posterior circulation cases were included, although lack of evidence supporting their inclusion and technical limitations inherent to imaging these vascular territories, mainly

due to the limited sensitivity of non-contrast computed tomography (CT) and CT perfusion in detecting acute infarctions in the posterior fossa for patient selection. The decision to pursue endovascular treatment was individualized through collaborative discussion among neuro-interventional, intensive care, and neurosurgical teams; however, all procedural and technical considerations were ultimately determined by the treating neuro-interventionalist.

## Endovascular technique

All procedures were performed under general anesthesia in a dedicated neuro-angiography suite. After femoral or radial artery access was established, baseline digital subtraction angiography (DSA) was conducted, followed by IA nimodipine or milrinone infusion (4 mg per affected vessel). The Comaneci device was then deployed in the anterior circulation, including M1–M2, A1–A4, and supraclinoid ICA segments, and posterior circulation P1-2, basilar, and V4 segment of the vertebral artery. The device was delivered via a 0.017- or 0.021-inch microcatheter, expanded gradually under fluoroscopic guidance, maintained in full expansion for ~120 seconds, and then withdrawn or repositioned as needed. While fully deployed, IA nimodipine or milrinone infusion was administered through the guiding catheter. The majority of interventions included intra-procedural heparin administration (in all cases, the activated clotting time was maintained at approximately twice from baseline). For proximal vasospasm, a primary intention-to-treat approach utilizing the Comaneci device remained standard practice, typically employing the Comaneci 21 or Comaneci Petit variants, rather than conventional balloon angioplasty. Hemodynamic targets included a mean arterial pressure (MAP) > 90 mmHg throughout the procedure. The interval from aSAH to vasospasm onset varied among patients.

## Outcomes and definitions

Primary study endpoints included angiographic efficacy, defined as measurable improvement in vessel diameter following angioplasty, and the absence of new infarction on follow-up non-contrast head CT. An additional primary endpoint related to immediate clinical response, defined as resolution, improvement, or no change of vasospasm-related symptoms. Perfusion imaging was deliberately avoided in the decision-making process, given the frequent bilateral hemispheric involvement, which could compromise the reliability of perfusion findings. Retreatment was defined as a repeated endovascular procedure performed in the same arterial segment that had been treated during a previous session. Procedures targeting different vascular territories or newly affected vessels were not considered retreatments. Secondary endpoints comprised the need for retreatment and procedural safety, specifically intra-procedural complications such as vessel perforation, inadequate visibility during deployment, and device overexpansion. Overexpansion was defined as the point at which the tip of the device began to exhibit subtle up and down movements observed under DSA during the gradual deployment of the Comaneci device, or alternatively, when the diameter of the mesh at its central portion reached the original diameter of the target artery. The

radial force was considered adequate when, under fluoroscopic visualization, the central struts of the Comaneci device appeared sufficiently expanded, indicating effective opening within the stenotic arterial segment. This imaging-based assessment ensured that the device provided enough luminal support to restore flow without exerting excessive mechanical stress on the vessel wall.

The primary radiological outcome was procedural success, defined as angiographic improvement assessed on a vasospasm severity scale: grade 0 (fully opened vessel), grade 1 (>0%–25% luminal narrowing), grade 2 (25%–50%), grade 3 (50%–75%), and grade 4 (>75% critical narrowing). Significant vasospasm reduction was defined as an improvement of two or more points on this scale post-treatment. The angiographic scale was adopted from the grading scale previously described initially by Salem et al.<sup>8</sup> Treatment failure was defined based on angiographic response to initial endovascular therapy and subsequent follow-up imaging. Primary failure was characterized by the absence of any detectable improvement or improvement in or only a one-point decrease in the vasospasm severity score in vessel caliber on angiography immediately following the procedure. Secondary failure was defined as recurrent vasospasm noted on follow-up angiography after initial angiographic improvement, thus necessitating further endovascular intervention.

### Data collection

Comprehensive clinical and imaging data were prospectively recorded for each patient, including demographics (age, sex, and baseline medical comorbidities), and specific aneurysm characteristics such as anatomical location, Hunt and Hess scale (HHS), and modified Fisher scale (mFS). Treated vessel segments within the circle of Willis were categorized as follows: proximal segments encompassing the supraclinoid of the internal carotid artery (ICA), anterior cerebral artery (ACA) A1, posterior cerebral artery (PCA) P1; or distal, referring to segments beyond these predefined locations, including MCA M2, ACA A2–A4, and PCA P2 segments. Detailed procedural variables were meticulously documented, including aneurysm securing strategies, the specific IA therapies utilized, the type of Comaneci device employed, anatomical sites of vessel dilation, the number of vessel dilations per device, and pre- and post-treatment vasospasm severity scores per treated vessel. Device-associated complications occurring intra- or post-procedurally were carefully recorded. Clinical presentation and neurological symptoms before and after treatment were documented. Additionally, retreatment information was systematically collected, including incidence, therapeutic modalities applied, timing of interventions, targeted vessel segments, and classification as primary or secondary treatment failures according to previously established criteria.

### Selection criteria and follow-up period

All patients underwent control CT according to clinical status (during the acute stage), with a mean of 6 days following the onset of SAH, to determine the occurrence of delayed cerebral ischemia (DCI) by comparing these findings with admission imaging. DCI was defined as the presence of a new cerebral infarction identified by ischemic changes in CT imaging and

findings compatible with vasospasm in CTA. Importantly, new cerebral infarction must not have been evident on imaging conducted 24–48 hours following early aneurysm occlusion and should not be attributable to alternative etiologies, such as endovascular intervention. An additional selection criterion was clinical deterioration, manifested by a decrease in the level of consciousness or the new onset of significant focal weakness. In our study, the patient with the shortest follow-up period was monitored for ~9 days from ictus (she deceased during hospitalization), whereas the longest follow-up extended up to 3 years, with a mean follow-up duration of 7.8 months.

### Statistical analysis

Continuous variables are summarized as mean  $\pm$  standard deviation (SD) or median and interquartile range (IQR), depending on the normality of data distribution. Specifically, patient age and intervals such as days between SAH and initial vasospasm treatment, number of dilations per vessel, and number of vessels treated per patient are reported as medians with interquartile ranges. Categorical variables, including demographic characteristics, comorbidities, aneurysm location, Hunt and Hess grading, modified Fisher score, procedural devices, treated vessel segments, and vasospasm severity grading, are expressed as frequencies and percentages.

### Safety of Comaneci angioplasty

Procedural safety was evaluated by systematically reviewing serial angiograms performed daily throughout the vasospastic period. We employed a multimodal imaging strategy, integrating DSA and CT to detect potential complications including embolic events, arterial dissection, vessel perforation, worsening vasospasm, and occlusion of the treated artery.

### Inclusion and exclusion criteria

Inclusion criteria included patients with intracranial vasospasm requiring endovascular mechanical intervention using the Comaneci device following unsuccessful medical management or IA dilator therapy. Endovascular treatment was performed only in cases of significant clinical deterioration, such as decreased level of consciousness, somnolence, new-onset hemiplegia or unilateral weakness, aphasia, impaired comprehension, or evidence of new infarct accumulation on daily follow-up CT imaging, indicating failure of conservative management. The selection of microwires, microcatheters, and guide catheters was left to the discretion of the main operator (GR). Likewise, the choice among various versions of the device (Comaneci-17, Comaneci-21, and Comaneci Petit) was determined by the dimensions of the affected vessel, as assessed by standard angiographic imaging.

## Results

### Baseline characteristics

Between January 2019 and November 2024, 891 patients presented with aSAH. Our cohort includes 14 patients treated at our institution with Comaneci-assisted angioplasty (CAA)

**Table 1.** Baseline patient characteristics ( $n = 14$ ).

Female	12 (85.7%)
Age, years (median, IQR)	63 (55–70)
Active smoking $n$ (%)	3 (21.42%)
Comorbidities	
Hypertension $n$ (%)	6 (42.8%)
Aneurysm multiplicity $n$ (%)	2 (14.28%)
Aneurysm location $n$ (%)	
Anterior circulation (64.5%)	
Acom	5 (35.8%)
ACA (A4–A5, pericallosal)	2 (14.3%)
MCA	1 (7.2%)
Pcom	1 (7.2%)
Posterior circulation (35.5%)	
PICA	1 (7.1%)
BA	2 (14.2%)
PCA	1 (7.1%)
Non-aneurysmal SAH	1 (7.1%)
Hunt and Hess $n$ (%)	
1	3 (21.4%)
2	3 (21.4%)
3	4 (28.6%)
4	4 (28.6%)
5	0
Modified Fisher $n$ (%)	
1	0
2	0
3	4 (28.5%)
4	10 (71.5%)

IQR: interquartile range; ACA: anterior cerebral artery; MCA: middle cerebral artery; PCA: posterior cerebral artery; SAH: subarachnoid hemorrhage.

for refractory vasospasm. The median patient age was 63 years (range of 55–70), with female predominance (85.7%) of the cohort. Hypertension was identified as the predominant comorbidity, affecting 42.8% of patients, while active smoking was present in 21.42% of the group. SAH represented the primary cause of vasospasm in all cases, with aneurysmal rupture accounting for 92.9% of these events; the remaining 7.1% refers to a single patient who developed non-aneurysmal subarachnoid hemorrhage with no identifiable bleeding source on both the initial and repeat angiographic studies performed on admission and one week later. Aneurysms predominantly involved the anterior circulation (64.5%), most commonly originating from Acom (35.8%). The mean Hunt and Hess score was 2.6, and the mean Fisher score was 3.7. Comprehensive baseline patient characteristics are detailed in Table 1.

### Endovascular treatment details

Procedural data are summarized in Table 2. A total of 96 vessel segments were treated, with distal segments comprising the majority (54.1%), including M2, A2–A4, and P2 segments, while the A4 segment represented the most distal site treated in 4.2% of cases. The median interval from SAH onset to the performance of endovascular treatment for vasospasm was 6.5 days (range 4–8 days). An equal proportion of patients (42.8%,  $n = 6$ ) developed vasospasm either early (within the initial 2 days post-SAH) or during an intermediate period (3–7 days post-SAH). A smaller group of patients (14.2%,  $n = 2$ ) presented with vasospasm

later, beyond 7 days following the hemorrhagic event. IA vasodilator therapy was administered prior to deployment of the Comaneci device in 85.6% of patients, with milrinone being the most utilized medication (64.2%). The remaining patients (14.4%) were treated directly with the Comaneci as the first-line therapy, as they were hemodynamically unstable, making IA vasodilator administration infeasible. The Comaneci-17 device was predominantly employed (92.8% of procedures), and combinations of devices, typically Comaneci-17 and Comaneci Petit, were used in approximately one-third of cases (28.6%). A trans-radial access approach was utilized in a single patient (7%). On average, each vessel required 1.5 device deployments, with a mean of 6.7 vessel segments dilated per patient. The anterior circulation was predominantly targeted (79.1%), with the M2 segment representing the most frequently treated site (36.4%). Prior to mechanical dilation with the Comaneci device, 59.5% of segments had critical vasospasm (grade 4), and an additional 29.1% exhibited severe stenosis (grade 3). A representative case demonstrating the use of the Comaneci device in distal vasospasm treatment is presented in Figure 1.

### Angiographic outcome

Overall, significant improvement in vasospasm severity was observed in 92.7% (89 of 96 treated vessels), and at least one-grade improvement in vasospasm severity score occurred in 98.9% of vessels (no improvement in only one vessel out of 96). This is further illustrated by the reduction in vasospasm severity scores presented in Figure 2. Importantly, no treated vessel segments exhibited worsening vasospasm following the procedure. Regarding 24-hour post-procedural vasospasm resolution, complete or near-complete resolution (defined as return to baseline vessel diameter or grade 1 vasospasm severity score, respectively) was achieved in 80.2% of the treated vessel segments (56.3% showed no vasospasm at all), whereas 17.7% demonstrated residual grade 2 vasospasm. The short-term durability of the treatment was unexpectedly high, with only 8.3% (eight out of 96) of treated segments requiring retreatment, of which only five were re-treated using the Comaneci device. Primary treatment failure occurred in seven out of 96 treated segments (7.2%), affecting four out of 14 patients (28.5%). The median number of treatment sessions per patient was 3. Evidence of infarcted tissue within the vascular territory of the treated vessels was observed in eight out of 14 patients (57.1% of our cohort). Angiographic outcomes are summarized in Table 3.

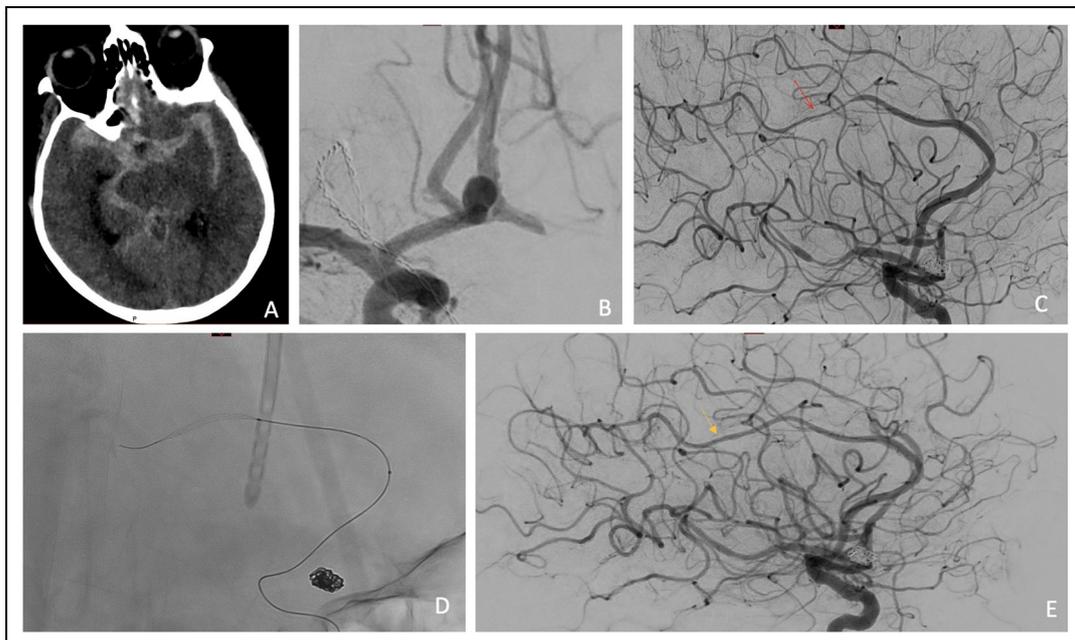
### Clinical outcome

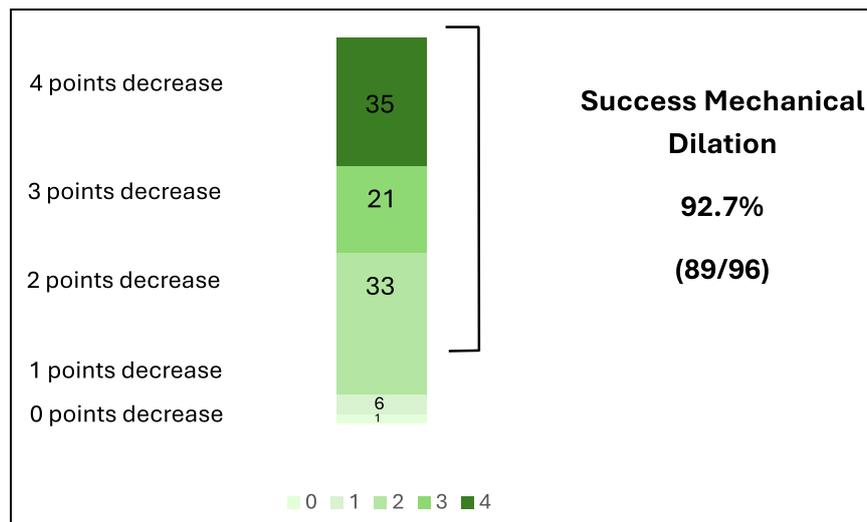
Clinical outcomes following CAA were evaluated in 14 patients. Complete resolution of post-treatment neurological symptoms was observed in two patients (14.3%), while seven patients (50%) experienced partial improvement with residual symptoms. Four patients (28.6%) demonstrated no clinical change following the intervention. Functional outcome, assessed using the modified Rankin Scale (mRS), was favorable (mRS 0–2) in four patients (28.6%), whereas the remaining 10 patients (71.4%) had poor outcomes (mRS 3–5). Mortality rate was 21.4% (3/14 patients).

**Table 2.** Procedural data.

Days between SAH and first vasospasm treatment, median (IQR)	6.5 (4–8)		
SAH-vasospasm Interval, days, <i>n</i> /total patients (%)			
0–2	2 (14.2%)		
3–7	6 (42.8%)		
>7	6 (42.8%)		
Intra-arterial vasodilator therapy, <i>n</i> /total patients (%)			
Nimodipine	3 (21.4%)		
Milrinone	9 (64.2%)		
None	2 (14.4%)		
Devices in use			
Comaneci 17	13 (92.8%)		
Comaneci Petit	5 (35.7%)		
Comaneci 21	1 (7.1%)		
Combined devices	4 (28.57%)		
Trans-radial approach (TRA)	1 (7%)		
Total vessels treated	<i>n</i> = 96		
Number of dilations per vessel, mean (IQR)	1.5 (1–3)		
Number of vessels dilated per patient, mean (IQR)	6.7 (5–8)		
Treated segment, <i>n</i> (%)			
Proximal segments (ICA, M1, A1, P1, BA, and V4)	44 (45.8%)		
Distal segments (M2, A2–A4, and P2)	52 (54.1%)		
Anterior circulation, <i>n</i> (% from total)	76 (79.1%)		
M1	10 (10.4%)		
M2	35 (36.4%)		
A1	16 (16.6%)		
A2	9 (9.4%)		
A4	4 (4.2%)		
ICA	2 (2.1%)		
Posterior circulation, <i>n</i> (% from total)	20 (20.9%)		
P1	7 (7.3%)		
P2	4 (4.2%)		
BA	7 (7.3%)		
V4	2 (2.1%)		
Vasospasm severity scale (pre-treatment), <i>n</i> /total vessels (%)	Proximal ( <i>n</i> = 44)	Distal ( <i>n</i> = 52)	Total ( <i>n</i> = 96)
1: 0%–25%	0	0	0
2: 25%–50%	7 (15.9%)	4 (7.6%)	11 (11.4%)
3: 50%–75%	9 (20.5%)	19 (36.5%)	28 (29.1%)
4: 75%–100%	28 (63.6%)	29 (55.9%)	57 (59.5%)

SAH: subarachnoid hemorrhage; IQR: interquartile range.

**Figure 1.** Illustrative case of Comaneci-assisted angioplasty (CAA) for distal cerebral vasospasm.



**Figure 2.** Drop in points of the vasospasm severity scale following Comaneci angioplasty (n).

**Table 3.** Angiographic outcome.

Vasospasm severity scale (post-treatment), n/total vessels (%)	Proximal (n = 44)	Distal (n = 52)	Total (n = 96)
0: (no-vasospasm)	25 (56.9%)	27 (51.9%)	52 (54.2%)
1: 0%–25%	8 (18.2%)	17 (32.7%)	25 (26%)
2: 25%–50%	9 (20.4%)	8 (15.4%)	17 (17.7%)
3: 50%–75%	2 (4.5%)	0	2 (2.1%)
4: 75%–100%	0	0	0
Significant vasospasm drop <sup>a</sup> , n/total vessels (%)	Proximal 40/44 (90.9%)	Distal 49/52 (94.2%)	Total 89/96 (92.7%)
Procedural complications, n/total vessels (%)			
Temporary vessel occlusion			1 (1%)
Vessel perforation			0 (0%)
Retreatment n/total vessels (%)	Proximal 3 (3.1%)	Distal 5 (5.2%)	Total 8/96 (8.3%)
IA vasodilators + balloon angioplasty, n			2
IA vasodilators only, n			3
Balloon angioplasty only, n			3
Repeat Comaneci assisted angioplasty, n			5
Primary treatment failure			
Patients, n/total patients (%)			4/14 (28.5%)
Vessels, n/total vessels (%)			7/96 (7.2%)
Number of treatment sessions per patient, median			3
Infarcted tissue in the treated vessels territory, n/total patients (%)			8/14 (57.1%)

<sup>a</sup>From 3–4 pre- to 0–2 posttreatment.

Mean duration of clinical follow-up was 7.8 months (range 13 days to 3 years), and mean mRS at the last follow-up was 3.6. Clinical outcomes are presented in Table 4.

### Complications

No permanent device-related procedural complications, such as vessel perforation, dissection, or vessel occlusion, were observed among any of the patients following mechanical dilation with the Comaneci device. In our cohort, no thromboembolic events, delayed infarcts attributable to the procedure, or device malfunctions were encountered. One case of transient intra-procedural vessel occlusion occurred

and was promptly successfully managed with contact aspiration, resulting in no evidence of new brain ischemia in the involved territory, and no residual neurological deficit. This case is presented in Figure 3. These findings support the overall safety profile of the Comaneci device in the treatment of refractory vasospasm, particularly in distal cerebral vessels, where traditional balloon angioplasty is associated with increased procedural risk.

### Discussion

Our study assessed the effectiveness and safety of the Comaneci device for mechanical angioplasty in patients

**Table 4.** Clinical outcome.

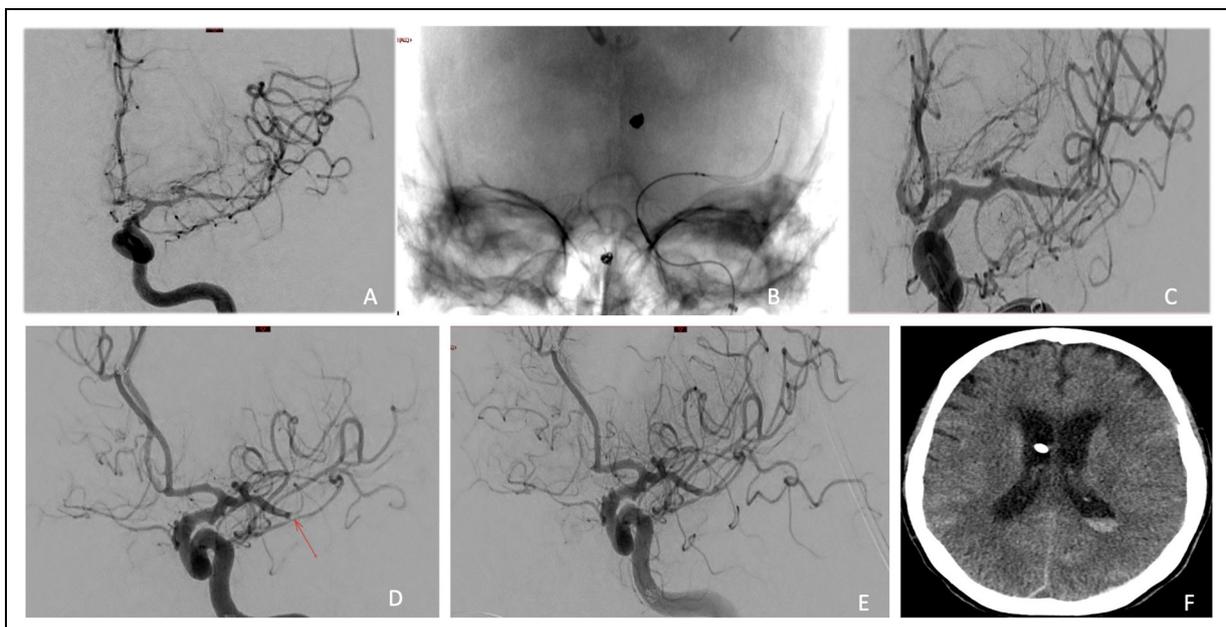
Post-treatment symptoms, n/total patients (%)	
Resolved	2/14 (14.3%)
Improved (with residual symptoms)	7/14 (50%)
Same (no change)	4/14 (28.6%)
Good outcome (mRS 0–2)	4/14 (28.6%)
Poor outcome (mRS 3–5)	10/14 (71.4%)
Mortality, n/total (%)	3/14 (21.4%)
Duration of follow-up, months, mean	7.8
mRS last follow-up, mean	3.6

mRS: modified Rankin Scale.

experiencing medically refractory cerebral vasospasm following aSAH. Traditionally, endovascular approaches for refractory vasospasm have primarily included IA vasodilator infusions and balloon angioplasty. The benefit of IA vasodilators is limited by temporary effects and significant systemic risks such as severe hypotension, increased intracranial pressure, and renal or pulmonary adverse events. Balloon angioplasty, introduced in the mid-1980s,<sup>9</sup> generally achieves satisfactory angiographic improvement but is associated with substantial procedural complications, including vessel injury (dissection or perforation) and thromboembolic events, with complication rates reported as high as 15%.<sup>10</sup> Furthermore, balloon dilation is technically challenging in distal or tortuous arterial segments, emphasizing the necessity for alternative treatment options.

Our results underscore several distinct advantages of the Comaneci device. Its unique design facilitates incremental and controlled mechanical dilation while preserving antegrade blood flow, significantly enhancing procedural safety relative to traditional balloon angioplasty. Importantly, no permanent procedural complications, such as vessel rupture, embolism, or arterial dissection, occurred in our patient cohort. A solitary event of transient intra-procedural vessel occlusion was effectively resolved through immediate contact aspiration, with no clinical sequelae.

In terms of angiographic effectiveness, the Comaneci device achieved substantial vasospasm reduction in 92.7% of treated segments. A key distinguishing feature of our study lies in its primary focus on distal vascular interventions, including segments such as M2, A2–A4, and P2, which are often considered technically challenging and high-risk for conventional balloon angioplasty. In contrast to previous studies that predominantly addressed proximal vasospasm,<sup>10</sup> our findings demonstrate the feasibility, safety, and efficacy of the Comaneci device in more distal cerebral vessels, thereby expanding the therapeutic scope of endovascular management in this complex clinical setting. Notably, over half of all treated vessels in our cohort underwent successful distal vessel intervention (52/96, 54.1%), emphasizing the practical value of this approach in a population typically underserved by standard techniques. In the present study, the Comaneci device was employed as the first-line modality for both proximal and distal mechanical dilatation, with balloon angioplasty reserved for cases in which the Comaneci approach was unsuccessful. Notably, the device demonstrated successful navigation into distal segments beyond the circle of Willis in more than half of our interventions, segments that are often challenging to access using conventional balloon techniques, ~50% of patients with distal vasospasm were not treated with the Comaneci due to navigation difficulties, lack of safe endovascular access, or microcatheter limitations, as the minimum I.D. of 0.017 inches does not always permit distal navigation (i.e. beyond M3 angiographic angle). These findings are consistent with previously published data,<sup>8,10–12</sup> including the COMMAND multicenter study,<sup>8</sup> reporting success rates of ~89.9% (overall including proximal and distal segments), which similarly highlighted the feasibility and efficacy of the Comaneci device in managing vasospasm in anatomically challenging vascular territories. Currently, there is no established treatment option for distal vasospasm following failure of medical therapy (including IA vasodilator administration), as balloon angioplasty in distal segments carries a substantially

**Figure 3.** Example of complication.

higher risk compared to more proximal vessels and is not considered a routine approach. Therefore, the fact that mechanical access and treatment were achieved in ~50% of these distal cases represents, in our view, an important initial and pioneering experience in managing this challenging condition involving distal arterial segments.

Distal CAA in the posterior circulation, specifically in the P2–P4 segments, was performed in ~4.2% of cases in our study, compared to only 2.4% in the COMMAND study.<sup>8</sup> Despite impressive short-term angiographic results, the long-term durability of CAA remains an area for further consideration. In our study, the retreatment rate was 8.3%, which is lower than the 12.4% reported in the COMMAND study.<sup>8</sup> All significant findings from our study were compared to previously published data, as summarized in Table 5.

In our study, 28.6% of patients achieved a favorable clinical outcome, despite a substantial proportion (57.2%) presenting with high-grade hemorrhage (Hunt and Hess score >3), indicative of severe initial clinical status. In comparison, the COMMAND study reported a higher favorable outcome rate of 51.5%, although an even greater proportion of patients (70.2%) had a Hunt and Hess score >3. This discrepancy may be explained by differences in patient and angiographic characteristics. Notably, our cohort included an older population (median age 63 years across 14 patients), compared to a younger cohort in the COMMAND study (median age 52 years across 40 patients). Additionally, our study demonstrated a significantly higher rate of distal vasospasm involvement (54.1% vs. 25%), which may represent more technically challenging lesions and contribute to the lower rate of favorable outcomes.<sup>8</sup> The observed mortality rate of 21.4% is consistent with previously published data, highlighting the persistent challenges in managing severe, refractory vasospasm following aSAH.

This study has several important limitations that should be acknowledged. First, the retrospective design and the relatively small sample size reduce the statistical power and limit the ability to draw definitive conclusions. Second, the lack of an independent imaging review by a second neuro-interventionalist represents a methodological limitation, potentially introducing operator-dependent bias in the assessment of procedural and angiographic outcomes. Third, the absence of a control group, either untreated or treated with conventional balloon angioplasty precludes direct comparison of the Comaneci device with standard therapies, thereby limiting the contextual interpretation of its efficacy and safety. Fourth, a limitation of our study is the small number of patients ( $n = 14$ ); however, a total of ~100 arterial interventions were performed. While part of the analysis was conducted per treated vessel segment rather than per patient, this approach was chosen to reflect the technical experience of the procedure, focusing on both safety and efficacy. Reporting data per vessel segment provides a more detailed representation of the overall angiographic success and safety profile. Nevertheless, not all analyses were based solely on vessel count; some variables were calculated per patient, allowing a more balanced assessment of both technical and clinical outcomes.

While our findings suggest that the Comaneci device is a viable and promising alternative to conventional angioplasty, particularly in anatomically challenging distal cerebral vessels, these conclusions should be interpreted with caution.

**Table 5.** Comparison of selected published series utilizing the Comaneci device for endovascular treatment of cerebral vasospasm following aneurysmal subarachnoid hemorrhage.

Journal, year	Number of patients (n)	Number of treated vessels (n)	mFisher scale (median)	Age (median, IQR)	Posterior circulation % (n)	Distal CAA % (n/total)	Retreatment rate % (n/total)	Good angiographic outcome % (n/total)	Favorable Clinical outcome % (n)	Complications % (n)	Mortality % (n/total)
Guenego et al. <sup>13</sup>	7	35	4	54 (47–64)	None	54% (19/35)	12.4% (16/129)	89% (31/35)	N/A	6% (2)	N/A
Salem et al. <sup>8</sup>	40	129	3.4	52 (35–57)	15.5% (20)	25% (32/129)	12.4% (16/129)	89.9% (98/109)	51.5% (17)	5% (2)	18.2% (6/40)
Thiery et al. <sup>14</sup>	18	54	3.5	57.53 (N/A)	None	57.4% (31/54)	N/A	71% (22/31)	N/A	5.5% (1)	5.55% (1/18)
<b>Our cohort</b>	<b>14</b>	<b>96</b>	<b>3.7</b>	<b>63 (55–70)</b>	<b>20.9% (18)</b>	<b>54.1% (52/96)</b>	<b>8/96 (8.3%)</b>	<b>92.7% 89/96</b>	<b>28.6% (4)</b>	<b>None</b>	<b>21.4% (3/14)</b>

JNS: Journal of Neurosurgery; JBSR: Journal of the Belgian Society of Radiology; IQR: interquartile range, CAA: Comaneci-assisted angiography; N/A: not applicable/not available.

Future prospective multicenter studies with larger sample sizes, standardized protocols, and appropriate control arms are required to validate these results and refine the therapeutic role of the device in refractory vasospasm management.

## Conclusions

The Comaneci device demonstrates encouraging preliminary results as a feasible, safe, and effective tool for mechanical angioplasty in patients with refractory cerebral vasospasm following aneurysmal subarachnoid hemorrhage. In our experience, the device was particularly advantageous in distal vascular territories, offering a viable alternative where balloon angioplasty may be technically limited or carry higher procedural risks. The absence of major periprocedural complications and the high rate of angiographic improvement support its favorable safety profile. However, clinical outcomes were modest, likely reflecting the high severity of illness in our cohort, including advanced age and a high burden of distal vessel involvement. Nevertheless, prospective multicenter trials with standardized imaging adjudication and larger sample sizes are warranted to better define its clinical efficacy, long-term durability, and optimal indications.

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