Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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**Conclusions:** In this single-center, multisite cohort study, patients who underwent CAS for RI ICA stenosis experienced a higher number of reinterventions. Although CAS is safe and effective for this RI ICA stenosis cohort, careful surveillance is warranted.

**Author Disclosure:** C. Franco Mesa: Nothing to disclose.

**Performing Transcarotid Artery Revascularization Outside of Manufacturer’s Instructions for Use Is Safe but Has Higher Reintervention Rates**

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**Background:** We sought to evaluate perioperative and short-term outcomes between transcatheter artery revascularization (TCAR) procedures compliant with manufacturer’s instructions for use (IFU) versus procedures in violation of IFU.

**Methods:** We retrospectively evaluated patients undergoing TCAR within a single multispecialty group between December 2015 and February 2020. Patients without adequate preoperative imaging were excluded. IFU criteria include common carotid artery (CCA) diameter of 5–6 mm, ICA diameter of 6 to 9 mm, femoral venous access, carotid bifurcation to clavicle length of 5 cm, and absence of severe CCA disease at the puncture site. Patient selection warnings (PSW) included extensive lesion calcification, intraluminal thrombus, and ICA/CCA tortuosity. Primary end points included perioperative (30-day) major adverse events (ipsilateral stroke, transient ischemic attack, death, or myocardial infarction) and perioperative complications. Secondary end points included ipsilateral restenosis, neurologic events, and reinterventions.

**Results:** Two hundred seventeen procedures (85 symptomatic, 132 asymptomatic) were performed on 209 patients. One hundred ninety-eight procedures were IFU compliant, and 19 (8.8%) had IFU violation(s). IfU violations included length from clavicle to bifurcation (n = 5), CCA puncture site disease (n = 5), and other (n = 4). The IFU violation group had higher incidences of urgent or emergent procedures (26% vs 15%; P = 0.004) and prior ipsilateral CEA (42% vs 16%; P = 0.006). The perioperative major adverse event rate was 3.2% (n = 7), 3.0% within IFU (n = 6), three strokes, two transient ischemic attacks, one death) and 5.3% outside IFU (n = 1 death). (P = 0.63). There was one conversion to endarterectomy in each group (P < 0.05). There were no differences in other perioperative outcomes. Follow-up data >30 days was available for 196 of 217 procedures. Average follow-up time was 1.2 ± 1.0 years. Ipsilateral reintervention rates within 2 years were significantly higher off IFU (log-rank P = 0.04) (Fig). Other outcomes (stroke, transient ischemic attack, myocardial infarction, and in-stent restenosis) were equivalent. PSW infringement had no differences in early or late outcomes.

**Conclusions:** TCAR in patients with anatomy outside of the manufacturer’s IFU can be safely performed, but leads to higher rates of carotid reintervention. Larger sample size and long-term follow-up data is needed to identify risks of specific anatomic violations as well as long-term outcomes.

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**Symptomatic Extracranial Carotid Disease in COVID-19 Patients Is Related to Thrombus Formation**

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**Background:** Coronavirus disease-2019 (COVID-19) has been associated with an acquired hypercoagulable condition. This study was undertaken to review the clinical manifestations of COVID-related symptomatic extracranial carotid artery disease (ECCAD) and compare the carotid plaque composition of symptomatic COVID patients to non-COVID symptomatic patients with ECCAD.

**Methods:** All patients with neurologic manifestations attributed to ECCAD who had clinical diagnosis of COVID-19 were reviewed. The clinical presentation, outcome, and carotid plaque characteristics of all patients were reviewed, and compared to symptomatic ECCAD patients prior to the COVID era (Table). Plaque composition was determined by analysis of calcium volume (mm³) within the carotid lesion with computed tomography angiography (CTA) using VitreaCore (version 6.7.6001.1) with manual outlining of calcium within the carotid lesions.

**Results:** Between the period of March 28 and April 12, 2020, seven patients with COVID-19 were admitted with cerebrovascular manifestations (all ischemic strokes) related to carotid bifurcation lesions. Five patients were documented to have COVID-19 by nasal polymerase chain reaction, and two were clinically diagnosed. Two patients had significant clot in the contralateral carotid (Fig). In sic of the COVID patients (86%), their presenting symptom was the stroke, whereas one patient developed a stroke 24 hours after being admitted with respiratory symptoms. Three patients underwent procedural intervention. one with an open carotid thromboendarterectomy and two with macrovascular distal embolization. underwent percutaneous mechanical thrombectomy. The remaining four patients were treated with anticoagulation alone. Seven consecutive patients with strokes secondary to ECCAD were selected from the pre-COVID era for comparison (Fig). The calcium plaque volume was significantly lower in the COVID patients compared to non-COVID patients. 84 mm³ (mean) compared to 401 mm³ (mean) (P = 0.02).

**Fig. (A-1 and A-2)** A patient with coronavirus disease-2019 (COVIDD-19) with bilateral carotid clots (B-1) COVID patient with a left carotid lesion (blue arrow). Note the hypodense material consistent with thrombus. (B-2) A non-COVID patient with right extracranial disease (yellow arrow). Note the high amount of calcium.
Table. Patient characteristics

| Characteristics          | COVID (n = 7) | Non-COVID (n = 7) | P value |
|--------------------------|--------------|-------------------|---------|
| Age, years               | 68           | 65                | .6      |
| Male sex                 | 5 (71)       | 6 (86)            | .5      |
| DM                       | 4 (57)       | 4 (57)            | .8      |
| CAD                      | 0 (0)        | 3 (42)            | .1      |
| HTN                      | 4 (57)       | 6 (86)            | .1      |
| HC                       | 3 (42)       | 3 (42)            | .8      |
| TOB                      | 3 (42)       | 3 (42)            | .6      |
| LDL mg/dL                | 84           | 119               | .8      |
| Carotid stenosis, %      | 90 (50-100)  | 70 (50-99)        | .1      |
| National Institutes of   | 17           | 5                 | 3       |
| Health Stroke Scale, m   |              |                   |         |

Volume of calcium in plaque, mm³ 84 (0-232) 401 (25-695).02

Results: Demographic characteristics, hypertension, and diabetes were similar for both groups. The only difference between groups was that more p-AVF patients were already receiving hemodialysis (61% vs 47%; P < .05). p-AVFs had superior maturation rates at 6 weeks (65% vs 50%; P = .01). Primary patency rates were higher for s-AVF 12 months (86% vs 61%; P < .01); however, primary patency was comparable between the two groups at 24 months (52% vs 55%; P = .48). There was no significant difference in secondary patency rates at 12 (90% vs 91%) or 24 months (88% vs 91%). At 2 years of follow-up, the rate of percutaneous reinterventions was similar, but s-AVFs required more frequent surgical interventions (56% vs 17%; P = .01). Issues with wound healing and infections were more frequent for s-AVF (9% vs 0.9%; P < .01).

Conclusions: Fistulas created percutaneously with Ellipsys have superior maturation rates and similar patency with s-AVFs created in an experienced high-volume vascular surgery practice. pAVFs had a lower risk for wound healing issues, infection and surgical revision. Larger, prospective randomized multicenter studies are needed in order to confirm these findings.

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Outcomes of a Multimodality Program for Pseudoaneurysms in Dialysis Access

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Background: Maintenance of long-term arteriovenous access is an important component in the long-term care of the patient with end-stage renal disease. Arteriovenous access is associated in the longer term with development of pseudoaneurysms (PA). The aim of this study is to evaluate the outcomes of staged PA treatment in dialysis access arteriovenous fistulas (AVF).

Methods: A retrospective review of all patients over a 10-year period with primary autogenous AVF (radiocephalic, brachiocephalic, and brachiocephalic) was undertaken at a single center. Patients undergoing elective PA repair were identified and were categorized having one or two PA and undergoing single or two stage interventions resulting on the following groupings: open single PA, endovascular single PA, open one stage and two stage PA, and endovascular two PA repair PA modalities. The 30-day outcomes, cannulation failure, line placement reinsertion, and functional dialysis (continuous hemodialysis for 3 consecutive months) were examined.

Results: From January 1999 to December 2019, 2291 patients (67% female; mean age 61 ± 13 years) underwent primary AVF placement (22% radiocephalic, 53% brachiocephalic, and 45% brachiocephalic). The majority of patients were diabetic and Hispanic. Of these patients, 25% presented with PA that met requirements for intervention of these 527 patients. 22% underwent endovascular repair. 44% had a single PA and remainder (56%), had had two PA repairs (Table). The 30-day major adverse cardiovascular event and 30-day morbidity rates were equivalent across all modalities (Table). Early thrombosis was significantly different across intervention groups, which led to increase need for a tunneled catheter. Simultaneous treatment of two PA by either open or endovascular modalities resulted in an increased incidence of line placement and secondary procedures (Table). Functional dialysis at 5 years was equivalent across the modalities.

Conclusions: Open and endovascular interventions are successful therapeutic modalities for PA but staged rather than simultaneous repair.

Table.

|                          | Open single PA repair | Endo single PA repair | Open one stage 2 PA repair | Open two staged 2 PA repair | Endovascular one stage 2 PA repair | P value |
|--------------------------|-----------------------|-----------------------|-----------------------------|-----------------------------|-----------------------------------|---------|
| Patients, No.            | 153                   | 79                    | 116                         | 142                         | 37                                | .78     |
| 30-day major adverse coronary events | 0.7%                  | 1.3%                  | 1.7%                        | 0.7%                        | 2.7%                              | .98     |
| 30-Day morbidity         | 1.3%                  | 1.3%                  | 1.7%                        | 1.4%                        | 2.7%                              | .02     |
| Need for a tunneled line | 2%                    | 4%                    | 6%                          | 3%                          | 16%                               | .002    |
| 30-Day thrombosis        | 1.3%                  | 2.5%                  | 4.3%                        | 2.1%                        | 10.8%                             | .04     |
| 30-Day cannulation failure | 1.3%                  | 2.5%                  | 4.3%                        | 2.1%                        | 5.4%                              | .21     |
| No. of secondary interventions per year | 2.1                   | 2.3                   | 3.1                         | 2.7                         | 3.4                               | .42     |
| Functional dialysis at 5 years | 82.9%                | 79.9%                 | 75%                         | 79.9%                       | 69.9%                             | .42     |

PA. Pseudoaneurysm.