Overall patients in the postmarket study had slightly higher revascularization rates (84% vs 82%), procedural SAEs (5.8% vs 3%), and mRS ≤2 scores (40% vs 25%), while patients in the pivotal study had higher rates of sICH (11% vs 7.2%) and all-cause mortality (33% vs 22%). These results suggest that the postmarket experience of the Penumbra System is consistent with that from the preapproval pivotal trial. Follow-up for some patients is ongoing.

Eligibility for rt-PA Within a Population: The Effect of the ECASS-3 Trial

According to standard emergency department (ED) guidelines, ischemic stroke patients must present to an ED within <3 hours of symptom onset to be eligible for rt-PA therapy. The European Cooperative Acute Stroke Study-3 (ECASS-3) expanded this eligibility window to 4.5 hours but with additional exclusion criteria. Dawn Kleindorfer, MD, University of Cincinnati Hospital Neuroscience Institute, Cincinnati, OH, presented data in a poster that showed that even with this expanded time window, eligibility for rt-PA remains low—about 9% versus 8% for the older time window.

This retrospective, observational study reviewed the primary/secondary hospital ICD-9-CM codes 430 to 436 from the year 1999 at 17 acute care hospitals in the greater Cincinnati/Northern Kentucky region. Of the 2441 ischemic stroke patients who were identified, 1968 presented to an ED. Fifty-four percent (54%) of these patients were female, 19% were black, and 80% were white. The mean age of the patients was 72 years.

In addition to the standard medical, time, and severity exclusions for rt-PA, the ECASS-3 excludes patients who are aged >80 years, those with an NIHSS score >25, those who have both diabetes mellitus and prior stroke history, and patients who have been given previous anticoagulant therapy. The purpose of the study was to compare the number of patients that is eligible for rt-PA therapy using the standard and revised ECASS-3 time frames and exclusion criteria.

Of the 2441 adult inpatient and out-of-hospital ascertained ischemic strokes, 1968 presented to an emergency department (81%) in 1999, 519 (22%) arrived in the ED in <3 hours from symptom onset and 87 (3.6%) arrived in 3 to 4.5 hours. Of the patients who arrived at the ED in <3 hours, 225 (11.4%) were eligible for standard regimen rt-PA, which is 9.2% of all ischemic stroke patients. Of the 87 patients who arrived between 3 and 4.5 hours, 23 (0.94%) were eligible using standard rt-PA exclusions, and only 24 (1.2%) would have been eligible using the additional exclusion criteria from the ECASS-3. Prevalence of the exclusion criteria for the 3 to 4.5 hour patients are listed in Table 1.

Table 1. Eligibility for rt-PA within a Population of Ischemic Stroke Patients Arriving 3 to 4.5 Hours After Symptom Onset.*

Standard Criteria†	n(%)
Partial thromboplastin time >40 sec	2 (3.5)
Platelet count <100,000	0
Mild Stroke (NIHSS <5)	21 (24.1)
INR <1.5	4.(4.6)
Glucose <50	0
Glucose >400	2 (2.3)
Seizure at onset	0
History of aneurysm or arteriovenous malformation	0
History of recent stroke, ICH/SAH	0
History of recent CEA or CABG	0
Systolic BP>185 or distolic BP>110	21(24.1)
ECASS-3 Exclusion Criteria†	
Age >80 years	27 (31.0)
NIHSS >25	1 (1.5)
Diabetes + prior stroke	12 (13.8)
Any anticoagulant use	7 (8.1)

*Categories are not mutually exclusive

†Does not agree with text since the same patient could be excluded for multi-reasons

NIHSS=National Institute of Health Stroke Scale; INR=international normalized ratio; ICH=intracranial hemorrhage; SAH=subarachnoid hemorrhage; CEA=carotid endarterectomy; CABG=coronary artery bypass grafting.

Dr. Kleindorfer concluded that the ECASS-3 expanded time window does not increase stroke patient eligibility for rt-PA very much since the majority of hyperacute patients arrives at the ED in <2 hours. She estimated that only an additional 0.94% of all stroke patients would have been eligible using the expanded ECASS-3 criteria. The ECASS-3 criteria excludes a significant portion of stroke patients, especially those aged >80 years (31%). However, the increased time window may still have an impact on rt-PA treatment rates and should not be ignored.