Embolic Stroke of Undetermined Source
A Systematic Review and Clinical Update

Robert G. Hart, MD; Luciana Catanese, MD; Kanjana S. Perera, MBBS; George Ntaios, MD, PhD; Stuart J. Connolly, MD

Background and Purpose—Embolic stroke of undetermined source (ESUS) designates patients with nonlacunar cryptogenic ischemic strokes in whom embolism is the likely stroke mechanism. It has been hypothesized that anticoagulation is more efficacious than antiplatelet therapy for secondary stroke prevention in ESUS patients. We review available information about ESUS.

Methods—Systematic literature review to assess the frequency of ESUS, patient features, and prognosis using PubMed from 2014 to present, unrestricted by language.

Results—On the basis of 9 studies, the reported frequency of ESUS ranged from 9% to 25% of ischemic strokes, averaging 17%. From 8 studies involving 2045 ESUS patients, the mean age was 65 years and 42% were women; the mean NIH stroke score was 5 at stroke onset (4 studies, 1772 ESUS patients). Most (86%) ESUS patients were treated with antiplatelet therapy during follow-up, with the annualized recurrent stroke rate averaging 4.5% per year during a mean follow-up of 2.7 years (5 studies, 1605 ESUS patients).

Conclusions—ESUS comprises about 1 ischemic stroke in 6. Patients with ischemic stroke meeting criteria for ESUS were relatively young compared with other ischemic stroke subtypes and had, on average, minor strokes, consistent with small emboli. Retrospective methods of available studies limit confidence in stroke recurrence rates but support a substantial (>4% per year) rate of stroke recurrence during (mostly) antiplatelet therapy. There is an important need to define better antithrombotic prophylaxis for this frequently occurring subtype of ischemic stroke. (Stroke. 2017;48:867-872. DOI: 10.1161/STROKEAHA.116.016414.)

Key Words: diagnosis ■ embolism ■ prognosis ■ secondary prevention ■ stroke

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of ESUS diagnosis, completeness of the diagnostic evaluation of patients with cryptogenic stroke required for ESUS diagnosis, treatment cross-overs, or numbers lost-to-follow-up.

Frequency of ESUS
We identified 12 studies that reported the frequency of ESUS as a fraction of all ischemic strokes, with prevalences ranging from 7% to 42% (Table 2).

In the 2 studies15,16 reporting the lowest frequencies, most patients with ischemic stroke did not undergo cardiac rhythm monitoring required for the diagnosis of ESUS; the study reporting the highest ESUS frequency17 was restricted to young patients with stroke (18–55 years). In the remaining 9 studies, the reported frequency of ESUS ranged from 9% to 25%.12,14,18–23 with both weighted and unweighted average frequencies of 17%. In 1 study involving 19 different countries,

Table 1. Criteria for Diagnosis of Embolic Stroke of Undetermined Source (ESUS)∗

<table>
<thead>
<tr>
<th>Criteria</th>
<th>340 publications</th>
<th>256 excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ischemic stroke detected by CT or MRI that is not lacunar†</td>
<td>296 Pulled</td>
<td>31 duplicated</td>
</tr>
<tr>
<td>2. Absence of extracranial or intracranial atherosclerosis causing ≥50% luminal stenosis in arteries supplying the area of ischemia</td>
<td>12 Hand-search</td>
<td>219 had no search</td>
</tr>
<tr>
<td>3. No major risk cardioembolic source of embolism‡</td>
<td>49 identified</td>
<td>terms in Abstract, Title or Key words</td>
</tr>
<tr>
<td>4. No other specific cause of stroke identified (eg, arteritis, dissection, migraine/vasospasm, and drug abuse)</td>
<td>28 included</td>
<td>5 case reports</td>
</tr>
</tbody>
</table>

CT indicates computed tomography; and MRI, indicates magnetic resonance imaging.

∗Requires minimum diagnostic evaluation that includes cardiac rhythm monitoring for >24 hours with automated rhythm detection.
†Lacunar defined as a subcortical infarct ≤1.5 cm (≤2.0 cm on MRI diffusion images) in largest dimension, including on MRI diffusion-weighted images, and in the distribution of the small, penetrating cerebral arteries of the cerebral hemispheres and pons.
‡Permanent or paroxysmal atrial fibrillation, sustained atrial flutter, intracardiac thrombus, prosthetic cardiac valve, atrial myxoma or other cardiac tumors, mitral stenosis, recent (<4 weeks) myocardial infarction, left ventricular ejection fraction <30%, valvular vegetations, or infective endocarditis.

there was no observed difference in the frequency of ESUS across global regions.19

Patient Features of ESUS
Eight studies reported patient features of 2045 ESUS patients (Table 3). Pooling these studies, the mean age of ESUS patients was 65 years and 42% were women. ESUS patients were younger and with lower frequencies of conventional vascular risk factors than non-ESUS patients with ischemic stroke;13,15,16 in 1 study, ESUS patients were significantly younger than other patients with ischemic stroke even after patients with atrial fibrillation were excluded.19 Three studies reported that patent foramen ovale was present in 25%,19 28%,28 and 58%22 of ESUS patients who underwent transesophageal echocardiography. The NIH Stroke Scale score near ESUS onset averaged 5 based on 4 studies involving 1772 ESUS patients (Table 3).

Prognosis of ESUS Patients
Five studies that included 1605 ESUS patients provided data on the rate of recurrent stroke during follow-up of ESUS patients (Table 4). Most (86%) ESUS patients were treated with antiplatelet therapy during follow-up, and 13% were given oral anticoagulants. Incomplete reporting of lost-to-follow-up and unspecified selection for oral anticoagulant therapy confound available data; annualized recurrent stroke rates averaged 4.5% per year during a mean follow-up of 2.7 years (Table 4). ESUS patients had higher rates of stroke recurrence compared with non-ESUS patients in 2 studies.16,26 One study reported that atrial fibrillation was subsequently diagnosed in 29% of ESUS patients during 3.2 years of follow-up;13 in this study, for the diagnosis of ESUS, Holter ECG monitoring was used in 52% of ESUS patients and cardiac telemetry in most of the remainder.26,27

Additional Recent Information Relevant to the ESUS Construct or to Cryptogenic Stroke
On the basis of histopathologic analysis of specimens extracted by the endovascular treatment of acute stroke in ESUS patients, most thrombi were erythrocyte-rich (13%) or of mixed composition (80%), with platelet-rich thrombi in only 8%.28 In another study, thrombi extracted from ESUS patients more closely resembled cardioembolic clots versus noncardioembolic thrombi.29

In mid-2014, 2 high-quality studies reported that episodes (usually brief, lasting several minutes) of previously unrecognized atrial fibrillation could be detected in 10% to 20% of patients with cryptogenic ischemic stroke if the duration of cardiac monitoring was prolonged beyond 24 hours of Holter ECG monitoring.30,31 This has been confirmed by others,14,32,33 with the frequency of detection of atrial fibrillation directly related to the duration of cardiac rhythm monitoring. Stroke severity of ESUS patients who are later diagnosed with atrial fibrillation is similar to strokes in ESUS patients without atrial fibrillation.34

Left atrial myopathy/dysfunction unassociated with atrial fibrillation may be a cause of ESUS.35,36 Other studies have emphasized a relationship of nonstenotic cervical carotid artery
plaques with cryptogenic stroke and with ESUS. Wider availability of computed tomography imaging of the aortic arch allows assessment of aortic plaque without transesophageal echocardiography. There has been additional emphasis on occult cancer in patients with cryptogenic stroke.

### Discussion

Methodological limitations in existing studies likely contributed to relatively wide ranges in the estimated frequencies of ESUS patients, their features, and prognosis. About 17% of patients with ischemic stroke met criteria for ESUS based on studies published to date, but this may be an underestimate because several diagnostic tests are required to make a diagnosis of ESUS, and there has been incomplete diagnostic evaluation in all studies reported to date. The different types and duration of cardiac rhythm monitoring undertaken in the available studies influenced the frequency of detection of covert paroxysmal atrial fibrillation (that excludes ESUS) and

### Table 2. Frequency of ESUS*

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Population</th>
<th>Cardiac Rhythm Monitoring</th>
<th>% ESUS* (n)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ntaios et al¹³</td>
<td>Retrospective, single-center, inpt stroke registry, 1992–2011</td>
<td>2731 Greek pts with first ischemic stroke; mean age 71 y</td>
<td>71% inpt telemetry for 7 d or discharge; 52% 24 h Holter ECG</td>
<td>10 (275)</td>
<td>29% of ESUS pts had AF detected during f/up</td>
</tr>
<tr>
<td>Mahagne et al¹⁴</td>
<td>No details</td>
<td>1074 French pts, no details published</td>
<td>Holter ECG as inpt (mean 7 d)</td>
<td>23 (243)</td>
<td>28% ESUS if only a 24 h Holter ECG done</td>
</tr>
<tr>
<td>Li et al¹⁵</td>
<td>Population-based, ischemic stroke or TIA, 2002–2014</td>
<td>1607 strokes and 948 TIs in the UK; mean age 74 y</td>
<td>Ambulatory home monitoring in 20% first 8 y, 80% thereafter</td>
<td>7 (189)</td>
<td>Nonlacunar TIAs could be ESUS; most cryptogenic pts did not have the required cardiac rhythm monitoring</td>
</tr>
<tr>
<td>Putaala et al¹⁶</td>
<td>Retrospective, single center, inpts, 2010–2012</td>
<td>540 Finnish pts, mean age 69 y</td>
<td>44% continuous ECG monitoring</td>
<td>9 (46)</td>
<td>NAVIGATE ESUS trial criteria used. Most cryptogenic pts did not have the required cardiac rhythm monitoring</td>
</tr>
<tr>
<td>Ladeira et al¹⁷</td>
<td>Retrospective, single center, ages 18-55 y, 2010–2014</td>
<td>100 young Portuguese pts with ischemic stroke, mean age 46 y</td>
<td>NR</td>
<td>42 (42)</td>
<td>Minor risk potential cardioembolic sources not more frequent in young stroke patients with ESUS</td>
</tr>
<tr>
<td>Takasugi et al¹⁸</td>
<td>Retrospective, single center, 2012–2014</td>
<td>623 Japanese acute ischemic stroke pts; mean age NR</td>
<td>Continuous ECG monitoring for ≥3 days in all</td>
<td>13 (81)</td>
<td></td>
</tr>
<tr>
<td>Perera et al¹⁹</td>
<td>Retrospective, 19 international stroke units, 2014–2015</td>
<td>2144 pts with ischemic stroke; mean age 67 y</td>
<td>33% only inpt telemetry for ≥24 h, 59% 24 h Holter ECG, 8% ≥24 h monitoring</td>
<td>16 (351)</td>
<td>Excluding pts with incomplete diagnostic testing required for ESUS, 19% were ESUS</td>
</tr>
<tr>
<td>Montero et al²⁰</td>
<td>Retrospective, single-center stroke unit pts during 2010</td>
<td>318 Spanish pts with ischemic stroke; mean age NR</td>
<td>No details</td>
<td>19 (60)</td>
<td>Support for a cardioembolic mechanisms for most ESUS</td>
</tr>
<tr>
<td>Coutinho et al²¹</td>
<td>Retrospective, single-center stroke registry, 2012–2015</td>
<td>1038 Canadian pts with ischemic stroke, mean age NR</td>
<td>Minimum of 24 h of automated rhythm monitoring</td>
<td>12 (128)</td>
<td>Support for nonstenotic carotid plaques as causing ESUS</td>
</tr>
<tr>
<td>Ueno et al²²</td>
<td>Retrospective, single-center inpt stroke registry, 2008–2014</td>
<td>1158 Japanese pts with acute ischemic stroke, mean age NR</td>
<td>Cardiac telemetry ≥24 h</td>
<td>25 (292)</td>
<td></td>
</tr>
<tr>
<td>Masina et al¹²</td>
<td>Retrospective, single-center stroke unit, 2010–2012</td>
<td>337 Italian ischemic stroke pts, mean age 78 y†</td>
<td>72 h continuous inpt telemetry without automated rhythm detection</td>
<td>25 (84)</td>
<td>41 (49%) ESUS pts had minor risk cardioembolic sources identified by echocardiography</td>
</tr>
<tr>
<td>Arauz et al²³</td>
<td>Retrospective, single-center stroke registry, 2003–2015</td>
<td>1673 Mexican ischemic stroke pts, mean age NR</td>
<td>At least 24 h of Holter monitor</td>
<td>9 (149)</td>
<td>60 additional patients with aortic plaques were not ESUS due to incomplete evaluation</td>
</tr>
</tbody>
</table>

AF indicates atrial fibrillation; ESUS, embolic stroke of undetermined source; f/up, follow-up; inpt, inpatient (ie, during hospitalization); NAVIGATE, New Approach Rivaroxaban Inhibition of Factor Xa in a Global trial vs ASA to Prevent Embolism in ESUS; NR, not reported; pts, patients; and TIAs, transient ischemic attacks.

*ESUS criteria per Cryptogenic Stroke/ESUS International Working Group (Table 1) unless otherwise noted in the comments column.

†Additional unpublished information from Prof M. Masina (personal communication).
likely contributed further to the range of reported prevalences of ESUS\(^{14}\) (Table 2).

It remains uncertain what fraction of ESUS patients will have atrial fibrillation detected during long-term follow-up, nor is the pathophysiological relationship between late detection of brief episodes of atrial fibrillation and ESUS adequately understood. It is unclear whether brief episodes of atrial fibrillation detected weeks or months after ESUS are

### Table 3. Features of ESUS Patients*

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Mean age, y</th>
<th>Women, %</th>
<th>Median NIHSS Score</th>
<th>History of Hypertension, %</th>
<th>Diabetes Mellitus, %</th>
<th>PFO, %†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ntaios et al(^{13})</td>
<td>275</td>
<td>68</td>
<td>36</td>
<td>5</td>
<td>65</td>
<td>24</td>
<td>NR</td>
</tr>
<tr>
<td>Li et al(^{15})</td>
<td>189</td>
<td>65</td>
<td>47</td>
<td>NR</td>
<td>47</td>
<td>12</td>
<td>NR</td>
</tr>
<tr>
<td>Putaala et al(^{16})</td>
<td>46</td>
<td>62</td>
<td>43</td>
<td>5&lt;6</td>
<td>44</td>
<td>7</td>
<td>NR</td>
</tr>
<tr>
<td>Ntaios et al(^{24})†</td>
<td>1095</td>
<td>68</td>
<td>41</td>
<td>5</td>
<td>60</td>
<td>20</td>
<td>NR</td>
</tr>
<tr>
<td>Perera et al(^{19})</td>
<td>351</td>
<td>62</td>
<td>43</td>
<td>4</td>
<td>64</td>
<td>25</td>
<td>25§</td>
</tr>
<tr>
<td>Ueno et al(^{22}) ‖</td>
<td>177</td>
<td>64</td>
<td>28</td>
<td>3</td>
<td>66</td>
<td>32</td>
<td>58</td>
</tr>
<tr>
<td>Masina et al(^{12})¶</td>
<td>84</td>
<td>73</td>
<td>52</td>
<td>NR</td>
<td>74</td>
<td>17</td>
<td>NR</td>
</tr>
<tr>
<td>Arauz et al(^{23})#</td>
<td>149</td>
<td>44</td>
<td>49</td>
<td>7</td>
<td>25</td>
<td>9</td>
<td>NR</td>
</tr>
<tr>
<td>Pooled – unweighted average‡</td>
<td>2045</td>
<td>63</td>
<td>43</td>
<td>5</td>
<td>56</td>
<td>19</td>
<td>…</td>
</tr>
<tr>
<td>Pooled – weighted average‡</td>
<td>2045</td>
<td>65</td>
<td>42</td>
<td>5</td>
<td>58</td>
<td>20</td>
<td>…</td>
</tr>
</tbody>
</table>

ESUS indicates embolic stroke of undetermined source; NIHSS, National Institutes of Health Stroke Scale; NR, not reported; and PFO, patent foramen ovale.

*ESUS criteria per Cryptogenic Stroke/ESUS International Working Group (Table 1)\(^{1}\) if not otherwise specified under comments in Table 2. Ladeira et al\(^{13}\) involving young ESUS patients not included.

†Patients from Ntaios et al\(^{13}\) and Putaala et al\(^{16}\) were included in Ntaios et al.\(^{24}\)

§Katsanos et al\(^{25}\) reported PFO in 28% of 61 young ESUS patients who underwent transesophageal echocardiography.\(^{19}\)

‖Subgroup of 292 ESUS patients who underwent transesophageal echocardiography and had follow-up.

¶Additional unpublished information from Prof M. Masina (personal communication).

#Eighty-nine (60%) of the 149 ESUS patients included in Ntaios et al\(^{24}\) (A. Arauz, personal communication) and hence are double-counted.

### Table 4. Prognosis of ESUS Patients*

<table>
<thead>
<tr>
<th>Study</th>
<th>n/Mean Follow-Up (y)</th>
<th>Mean Age, y</th>
<th>Antithrombotic Therapy</th>
<th>AF During Follow-Up†</th>
<th>Stroke (Est Annualized Rate)†</th>
<th>Stroke, MI, Vascular Death (Est Annualized Rate)</th>
<th>Total Mortality (Est Annualized Rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ntaios et al(^{13,26})‡</td>
<td>275 (3.2)</td>
<td>68</td>
<td>74% APT only, 22% OAC</td>
<td>80 (29%)</td>
<td>6.8%/y</td>
<td>9.0%/y§</td>
<td>8.2%/y</td>
</tr>
<tr>
<td>Li et al(^{15})</td>
<td>189 (1)</td>
<td>65</td>
<td>NR</td>
<td>NR</td>
<td>=5%/y</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Putaala et al(^{16})‡</td>
<td>46 (1.8)</td>
<td>62</td>
<td>85% APT, 11% OAC</td>
<td>NR</td>
<td>5.1%/y</td>
<td>NR</td>
<td>1.3%/y</td>
</tr>
<tr>
<td>Ntaios et al(^{24})†</td>
<td>1095 (3.0)</td>
<td>68</td>
<td>87% APT only, 12% OAC</td>
<td>NR</td>
<td>4.8%/y^{</td>
<td>l}</td>
<td>NR</td>
</tr>
<tr>
<td>Masina et al(^{12})¶</td>
<td>84 (2.1)</td>
<td>73</td>
<td>99% APT</td>
<td>NR</td>
<td>2.3%/y</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Ueno et al(^{22})#</td>
<td>177 (3.5)</td>
<td>64</td>
<td>72% APT, 29% OAC</td>
<td>NR</td>
<td>3.9%/y</td>
<td>5.0%/y**</td>
<td>1.3%/y</td>
</tr>
<tr>
<td>Arauz et al(^{23})††</td>
<td>149 (2.3)</td>
<td>44</td>
<td>91% APT, 5% OAC</td>
<td>NR</td>
<td>2.3%/y</td>
<td>NR</td>
<td>0%/y</td>
</tr>
<tr>
<td>Pooled – unweighted average†, ††</td>
<td>1545 (2.4)</td>
<td>68</td>
<td>87% APT, 12% OAC</td>
<td>…</td>
<td>4.0%/y</td>
<td>…</td>
<td>2.9%/y</td>
</tr>
<tr>
<td>Pooled – weighted average†, ††</td>
<td>1605 (2.7)</td>
<td>65</td>
<td>86% APT, 13% OAC</td>
<td>…</td>
<td>4.5%/y</td>
<td>…</td>
<td>3.9%/y</td>
</tr>
</tbody>
</table>

AF indicates atrial fibrillation; APT, antiplatelet; Est, estimated; ESUS, embolic stroke of undetermined source; MI, myocardial infarction; NR, not reported; and OAC, oral anticoagulant.

*ESUS criteria per Cryptogenic Stroke/ESUS International Working Group (Table 1).\(^{1}\) See Table 2 for description of studies.

†Additionally, Mahagne et al\(^{14}\) reported AF identification in 2.1% and ischemia recurrence rate of 1.2% among 243 ESUS patients during a mean follow-up of 2.4 years, but no details about the study have been published.

‡Patients from Ntaios et al\(^{13}\) and Putaala et al\(^{16}\) were included in Ntaios et al.\(^{24}\)

§Recurrent stroke, MI, systemic embolism, ruptured aortic aneurysm, or sudden cardiac death.

‖Included ischemic stroke or transient ischemic attack.

¶Additional unpublished information from Prof M. Masina (personal communication).

#Subgroup of 292 ESUS patients who underwent transesophageal echocardiography and had follow-up.

**Included incident peripheral artery disease.

††Eighty-nine (60%) of the 149 ESUS patients included in Ntaios et al\(^{24}\) (A. Arauz, personal communication) and not included in unweighted analysis and adjusted for the weighted analysis.
relevant to stroke cause or identify patients who benefit from anticoagulation.

The mean age of ESUS patients (averaging 65 years) may reflect incomplete diagnostic investigation of older patients with stroke that permit the diagnosis of ESUS. With this caveat, the picture of ESUS patients that emerged is of relatively young (compared with atrial fibrillation-associated stroke) patients with mild strokes and with lower frequencies of conventional vascular risk factors compared with non-ESUS patients with ischemic stroke. We speculate that ESUS is usually caused by relatively smaller emboli from valvular and arterial sources rather than larger emboli originating in the cardiac chambers, notably left atrial appendage thrombi in patients with atrial fibrillation that embolize to cause large, devastating strokes. Most minor risk emboli sources hypothesized to underlie most ESUS typically produce small emboli.

Recurrent stroke during follow-up averaged 4.5% per year (Table 4), but this estimate is based on patient cohorts dating back to 1992 and limited by the retrospective design of available studies. Concomitant therapies have evolved, and stroke rates in secondary prevention trials have consistently declined during the past 25 years. Consequently, this estimate of stroke recurrence rate in ESUS patients may be an overestimate. However, ESUS patient features as characterized in this analysis resemble those of participants in 2 clinical trials who had recurrent stroke rates of 7% to 11% within 3 months after an index minor ischemic stroke when treated with aspirin. It is likely that absolute rates of recurrent stroke will differ among subgroups of ESUS patients according to patient age and comorbidities. Furthermore, it is currently unknown whether the stroke recurrence risk is particularly high in the initial weeks after an ESUS, and this, too, may vary with the presumed ESUS source (ie, PFO-associated ESUS versus aortic arch plaque-associated ESUS).

That most cryptogenic ischemic strokes are embolic is not a new concept. However, there has been little progress in the tic arch plaque-associated ESUS). The mean age of ESUS patients (averaging 65 years) may reflect incomplete diagnostic investigation of older patients with stroke. Furthermore, it is currently unknown whether the stroke recurrence risk is particularly high in the initial weeks after an ESUS, and this, too, may vary with the presumed ESUS source (ie, PFO-associated ESUS versus aortic arch plaque-associated ESUS).

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We are grateful to Dr M. Masina for kindly providing unpublished data.

Disclosures

All coauthors except Dr Catanese have received financial remuneration from Bayer AG for their participation in the NAVIGATE ESUS trial; In addition, Dr Ntafos has received speaker fees from Boehringer-Ingelheim, Bayer AG, and BMS/Pfizer and a research grant from Pfizer, and he is an advisory board member for Boehringer-Ingelheim. The other authors report no conflicts.

References


Predictors of finding occult atrial fibrillation after cryptogenic stroke.


