First-Year Results of a Community-Based Study of Stroke Incidence in Umbria, Italy

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The SEPIVAC study (Italian initials for "epidemiologic study of incidence of acute cerebrovascular disease") is a community-based epidemiologic survey of incidence and outcome of cerebrovascular disease in the territory of the 6th Local Health Unit, Umbria, Italy, where 49,101 people live. All cases were registered with the study either by notification from general practitioners or by check of hospital admission within the study area and in the two hospitals of Perugia. Death certificates were looked at as well. Patients were registered with the study when the clinical picture fulfilled the definition of stroke and transient ischemic attack (TIA) adopted for this study. Patients were followed up at approximately 30 days and 6 months. During the first year of the study (September 1, 1986 to August 31, 1987), 189 cases were registered: 108 suffered a "first ever in a lifetime" stroke, 30 a recurrent stroke, and 51 a "first ever in a lifetime" transient ischemic attack. Sixty-one percent of patients (71% of first strokes) had a computed tomography scan. For our study, the crude annual incidence rate of first stroke was 2.2 per 1,000 (confidence intervals 1.81-2.66); the standardized rate to the European population was 1.36 (confidence intervals 1.06-1.74). At least 83% of first strokes were due to cerebral ischemia; in 26 cases a clinical diagnosis of lacunar ischemia was made. The 30-day case fatality rate was 21%; 25% of our patients had recovered completely or almost completely after 1 month. (Stroke 1989;20:853-857)

Cerebrovascular disease (CD) still represents the most common cause of severe disability, and stroke patients consume a large part of health resources in the Western world. Accurate information about incidence, management, and outcome is needed for planning medical and social services and for secondary stroke prevention in the community.

Few population-based studies comprise all stroke cases from a defined population, and none has been done in Italy. We therefore thought it worth planning an incidence study of stroke based in the territory of the 6th Local Health Unit (USL, Italian initials) of Umbria, which is also called USL del Trasimeno (Figure 1). The study has been named SEPIVAC from the Italian initials for "epidemiologic study of incidence of acute cerebrovascular disease."

Subjects and Methods

The study population comprises all residents in USL 6 territory. We obtained data on residents as of December 31, 1986 from the official authorities of the Umbria region (Centro Regionale Elaborazione Dati). There were 49,101 people (23,915 males, 25,186 females) whose age distribution is shown in Figure 2. Their mean age appears higher than that of the populations of Umbria, Italy, and Europe as obtained from our national statistics (ISTAT, 1986).

The registration of patients began on September 1, 1986. We present here data on first-year incidence and 30-day and 6-month follow-up; however, the study was planned to run for 3 years.

Cases were registered with the study in one of the following ways: 1) Notification from the general practitioner (GP). In Italy, all persons living in the territory of one USL are registered with a GP, who
is also registered in that USL. All 38 GPs working in USL del Trasimeno formally agreed to collaborate with SEPIVAC. GPs were only requested to leave a message on a 24-hour phone-answering device. Every notified patient was assessed. 2) On-call medical service. Every notified patient was assessed. 3) Hospital admission registers of the three hospitals in USL 6 territory and of the two hospitals in Perugia, where a significant part of Trasimeno population is usually admitted because of both geographic location and tradition. Local hospitals were visited twice weekly, whereas the registers of Perugia hospitals were checked every week. Patients admitted with diagnosis of stroke, cerebrovascular insufficiency, paresis, and so forth, and those admitted with a diagnosis such as collapse, dizziness, coma, and so on, who resided in USL 6 territory were assessed. Nonresidents were registered separately, and we will not discuss those data in this report. 4) Death certificates were looked at every month. In this way we think we were able to register the occasional patient (e.g., those with subarachnoid hemorrhage [SAH]) who had died very quickly and those who had died after a stroke outside the study area but who were residents of Trasimeno territory. Patients who had suffered a stroke outside the study area and came back after having been treated in different hospitals were registered after GP notification. The study physicians attempted to see the patient as soon as possible after the notification. When the clinical picture fit the definition of TIA or stroke that we had agreed to adopt, the patient was registered with the study.

All clinical and laboratory data were reported on a special form, which was prepared from the one used in the Oxfordshire Community Stroke Project (OCSP). The visiting physician also arranged for electrocardiogram (ECG) and blood tests (home patients) and for computed tomography (CT) scan within 30 days and Doppler exam of carotid arteries (all patients). Unless requested, no advice on management was given. To ensure that diagnostic standards remained uniform, the study team met weekly to discuss each new case and definite diagnosis, and inclusion of cases were stated only after these meetings. At approximately 30 days and 6 months from the event, patients were reassessed and information on disability and new events was recorded on a follow-up form, which was also prepared from OCSP. Death causes were recorded as well, using all the available information from hospital forms, GPs, and relatives. Data were stored on an ad hoc prepared computer program and analyzed using standard statistical methods.

**Results**

During the first year of the study, 189 cases were registered. Of these cases, 108 suffered a “first ever in a lifetime” stroke (FELS), 30 a recurrent stroke, and 51 a “first ever in a lifetime” TIA (so named even if the patient had suffered a stroke before the TIA).

Twenty-three patients (12%) died before the study physician’s visit, and information was obtained from relatives, hospital physicians, and CT scans. Sixty-one percent of the patients (71% of FELS) had a CT scan. Nine patients with FELS (8.3%), six (20%) patients with recurrent stroke, and 11 (21.6%) with TIA were never admitted during the acute phase of their disease and were managed at home by their GPs. Table 1 shows the age and sex-specific rates for FELS during the first year of the study. The crude annual incidence rate for our study is 2.2 per 1,000 (confidence intervals 1.81-2.66). Table 2 shows the age specific rates compared with those obtained from other population-based studies. The rate standardized to the European population is 1.36 per 1,000 (confidence intervals 1.06-1.74).

In the 73 patients with FELS who had CT, the comparison with Allen score (>24 or <4) yielded 100% concordance. Thus, we thought we might classify the 108 cases of FELS as follows: definite infarction (CT diagnosis); probable infarction (CT not done, Allen score <4); not known (CT not done, Allen score >24 or <4); definite hemorrhage, including SAH (CT diagnosis or unequivocal lumbar puncture); and probable hemorrhage (CT not done, Allen score >24). Results are shown in Figure 3.

To summarize, cerebral ischemia accounted for at least 83% of our series. A clinical diagnosis of lacunar ischemia was done in 26 (24%) cases of FELS and was confirmed by CT (either normal or showing appropriate small, deep infarcts) in 20,
whereas CT was not done in four cases and revealed a large infarct in two cases.

As for follow-up of FELS, the 30-day case-fatality rate was 21% (23 of 108); 54% (58 of 108) of stroke patients were still disabled at 30 days (Rankin Scale ≥3),8,9 whereas 25% (27 of 108) had recovered completely or almost completely.

At 6 months the case-fatality rate was 33.3% (36 of 108), whereas 47 patients (43.5%) were still disabled. Three patients had a recurrent stroke during follow-up.

**Conclusion**

Several criteria for an ideal stroke-incidence study have been proposed,2 which must be fulfilled to allow comparison of a study's results with others published in the literature. Criteria include standard diagnosis, complete case ascertainment, prospective design, registration of FELS, classification of pathologic types of stroke, rates given for all pathologic types combined, a well-defined denominator and a large population, rates calculated for similar lengths of time, cases collected over whole years,

**TABLE 1. Age and Sex Incidence Rates (× 1000) for First Stroke in USL 6, Umbria, Italy, 1986–1987**

<table>
<thead>
<tr>
<th>Age</th>
<th>No. of cases</th>
<th>Rate</th>
<th>Confidence intervals (95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Men</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–54</td>
<td>7/16496</td>
<td>0.42</td>
<td>0.17–0.86</td>
</tr>
<tr>
<td>55–64</td>
<td>10/3484</td>
<td>2.87</td>
<td>1.38–5.28</td>
</tr>
<tr>
<td>65–74</td>
<td>15/2400</td>
<td>6.25</td>
<td>3.50–10.31</td>
</tr>
<tr>
<td>75–84</td>
<td>16/1321</td>
<td>12.11</td>
<td>6.93–19.62</td>
</tr>
<tr>
<td>85+</td>
<td>4/214</td>
<td>18.69</td>
<td>5.08–47.85</td>
</tr>
<tr>
<td><strong>Women</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–54</td>
<td>2/15988</td>
<td>0.13</td>
<td>0.02–0.47</td>
</tr>
<tr>
<td>55–64</td>
<td>4/3745</td>
<td>1.07</td>
<td>0.29–2.74</td>
</tr>
<tr>
<td>65–74</td>
<td>12/2931</td>
<td>4.09</td>
<td>2.11–7.16</td>
</tr>
<tr>
<td>75–84</td>
<td>25/2021</td>
<td>12.37</td>
<td>8.00–18.31</td>
</tr>
<tr>
<td>85+</td>
<td>13/501</td>
<td>25.95</td>
<td>13.80–44.38</td>
</tr>
<tr>
<td><strong>Men and women</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–54</td>
<td>9/32484</td>
<td>0.28</td>
<td>0.13–0.53</td>
</tr>
<tr>
<td>55–64</td>
<td>14/7229</td>
<td>1.94</td>
<td>1.06–3.26</td>
</tr>
<tr>
<td>65–74</td>
<td>27/5331</td>
<td>5.06</td>
<td>3.33–7.39</td>
</tr>
<tr>
<td>75–84</td>
<td>41/3342</td>
<td>12.27</td>
<td>8.80–16.64</td>
</tr>
<tr>
<td>85+</td>
<td>17/715</td>
<td>23.78</td>
<td>14.86–38.05</td>
</tr>
<tr>
<td><strong>Total men and women</strong></td>
<td></td>
<td></td>
<td>2.20</td>
</tr>
</tbody>
</table>

and standard presentation of rates by patient age and sex. Our study was planned taking into account all of those criteria. We therefore think that at the end of the study, planned for 1989, we will be able to compare our results with those of the other "ideal" studies that have been published.

Looking at the 1-year results, and standardizing for the European population, our incidence was 1.36 of 1,000 as compared with 1.53 of 1,000 of OCSP, although the confidence intervals overlap.

A stroke and TIA register not only has scientific and theoretic uses but offers invaluable information to those involved in planning health services, both in hospital and outpatient settings. For instance, information on recurrent stroke and hospital admissions of patients not residing in USL 6 is being used for planning special services. The results of the comparison of CT findings with the Allen score, if confirmed at the end of the study, will be used to reduce the number of requests for CT, and follow-up results will be used in planning an outpatient physiotherapy service.

As for our preliminary results, the 30-day case-fatality rate was lower than those reported in hospital series, and this is almost certainly because we have also collected very mild cases, treated both at home or in hospital for a few days. These figures appear very similar to those of other community-based studies.

It is possible that the TIA ascertainment was not complete, because cases of very short duration might have been overlooked by the patient or GP. Nevertheless, we discussed our project with GPs well in advance, and the special interest of both our group and the USL Administration on cerebrovascular disease is well known to every health operator in Trasimeno area. In this way, we hope we have reduced the number of "ignored" cases as much as possible.

The classification of pathologic types of strokes was achieved by means of the Allen score in a significant proportion of our cases. We are aware that other studies reached better results in these settings: for example, in OCSP 90% of patients had a pathologically definite diagnosis, whereas we were able to reach only 71%. Nevertheless, taking into account the 100% concordance with CT results that we obtained, we think that for epidemiologic purposes the Allen score can be safely used to separate infarctions from hemorrhages. Six "type not known" out of 108 cases, or 5.6%, is a reasonable price to pay for the unavoidable organization difficulties of studies like ours.

Finally, the number of lacunar syndromes we found was very similar to that in other studies. If this result is confirmed, future trials on stroke prevention and treatment should consider separating this different kind of cerebral ischemia.

Acknowledgments

We wish to thank Professor Charles Warlow, Edinburgh, and Doctor John Bamford, Leeds, for their invaluable help in preparing this paper. Also, we wish to thank all the colleagues involved in the OCSP for having allowed us to use their experience in our study.

This study would not have been possible without the kind cooperation of the health authorities and general practitioners of the USL 6 of Umbria.

Adapted from Malgren et al2 with permission.

![Figure 3](http://stroke.ahajournals.org/)

**FIGURE 3.** First stroke. DI, definite infarction; PI, probable infarction; NK, not known; DH, definite hemorrhage.
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KEY WORDS • cerebrovascular disorders • incidence • Italy
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