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*Published in:*  
Europace

*DOI:*  
[10.1093/europace/euu165](https://doi.org/10.1093/europace/euu165)

2014

[Link to publication](#)

### *Citation for published version (APA):*

Baturova, M., Lindgren, A., Carlson, J., Shubik, Y. V., Olsson, B., & Platonov, P. (2014). Atrial fibrillation in patients with ischaemic stroke in the Swedish national patient registers: how much do we miss? *Europace*, 16(12), 1714-1719. <https://doi.org/10.1093/europace/euu165>

*Total number of authors:*  
6

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## **Atrial fibrillation in patients with ischemic stroke in the Swedish national patient registers:**

### **How much do we miss?**

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Word count – 3388 words

## **Abstract**

**Aims:** Data from national discharge registers are commonly used to estimate prevalence and incidence of atrial fibrillation (AF) in epidemiology studies. However, sensitivity and specificity of register-based AF diagnosis have not been evaluated. We sought to assess the validity of AF diagnosis in the Swedish Patient Register against electrocardiography (ECG) documentation of AF.

**Methods:** The study sample comprised of 336 patients (median age 76 (interquartile range (IQR) 67-82 years, 136 female) with first-ever ischemic stroke, enrolled in the Lund Stroke Register from March 2001 to February 2002 and 1:1 age- and gender-matched control subjects without stroke from the population register. Data was exported from the Patient Register in October 2011 (end of follow-up). AF documentation by ECG was assessed using an electronic archive containing all ECGs taken in the hospital catchment area starting in 1988.

**Results:** A total of 7247 ECGs were reviewed, with the median number of ECGs per person being 7.5 (IQR 3-15). AF was detected by ECG in 190 patients; and in 188 patients by linkage with Patient Register. In most patients, AF was documented first by ECG data, with median time to register diagnosis being 16 days (IQR 3-859). Specificity of AF diagnosis in the Swedish Patient Register was 93%, sensitivity was 80%.

**Conclusion:** Despite the high specificity, AF diagnosis in the Swedish Patient Register assessed in the population of ischemic stroke patients and age- and gender-matched control subjects has modest sensitivity, which may result in underestimating prevalent and incident AF cases if only register data are used for identification of subjects with AF in epidemiology studies.

**Key words:** Atrial fibrillation, validity, Swedish Patient Register, sensitivity, specificity, electrocardiography.

### **Condensed abstract**

We assessed sensitivity and specificity of atrial fibrillation (AF) diagnosis in Swedish Patient Register against electrocardiography documentation in 672 patients from the Lund Stroke Register. Despite high specificity (93%), register-based AF diagnosis has modest sensitivity, resulting in underestimation of AF prevalence by 20% when using only register data.

### **What's new?**

- Though Swedish Patient Register is widely used for the assessment of atrial fibrillation (AF) prevalence and incidence in epidemiological studies, it is not known to what extent it underestimates AF prevalence. This is the first study in which the sensitivity and specificity of Swedish Patient Register-based AF diagnosis was evaluated against the electrocardiography documentation of AF in an unselected cohort of consecutively enrolled patients with ischemic stroke and control subjects.
- Despite high specificity, register-based AF diagnosis has modest sensitivity, which results in underestimation of AF prevalence and incidence when only register data are used.
- A time lapse exceeding 6 months between the first ECG documentation and AF registration in the Swedish Patient Register is noted for one third of patients, and should be considered when interpreting AF prevalence and incidence estimates using only the patient register data.

## **Introduction**

Atrial fibrillation (AF) is the most common cardiac arrhythmia in the general population, with a prevalence of at least 3% (1), which increases with age, reaching 15% in elderly people (2). AF is a major cause of mortality and morbidity due to ischemic stroke (3). The “gold standard” of AF diagnosis is electrocardiography (ECG) (2). However, in population-based studies, national discharge registers are commonly used as a simple and inexpensive data source to identify clinical end-points. Data from the Swedish Patient Register have been used in epidemiological studies to estimate AF prevalence, incidence and risk factors for ischemic stroke (1, 4, 5).

Whether or not national registers provide complete and accurate information about disease prevalence remains unclear. In previous studies, high Swedish Patient Register validity was reported for diagnosis of acute myocardial infarction and congestive heart failure (6, 7), with lower reported validity for less severe diseases, such as hypertension and lipid disorders (8).

Literature data on AF diagnosis validity in national registers are sparse, and to our knowledge, only one study assessed validity of AF diagnosis in the Swedish Patient Register (9). In that study validity was shown to be high when estimated in a randomly selected sample of 100 patients with a register-based AF diagnosis, verified by ECG data or by information from medical records (9). However, to the best of our knowledge, there has been no study reporting sensitivity and specificity of AF information contained in the Swedish Patient Register.

In the present study, we aimed to assess AF diagnosis validity in the Swedish Patient Register in an unselected sample of ischemic stroke patients and matched control subjects consecutively included in the Lund Stroke Register (10) and reported to have a high prevalence of AF through an analysis based on a comprehensive review of ECGs in a regional electronic ECG archive.

## **Materials and Methods**

### ***Study cohort***

The study sample comprised 336 first-ever ischemic stroke patients included in the Lund Stroke Register between March 1, 2001 and February 28, 2002 (median age 76, interquartile range (IQR) 67-82 years, 136 female) and 336 control subjects randomly selected from the same geographical region and matched to stroke cases for the year 2001 by age and gender in a 1:1 case-control manner using the Swedish Population Register, as previously described (10, 11). We followed up all study subjects until October 17, 2011. Data from the Swedish Patient Register regarding AF diagnosis for all included subjects up to this date was also collected. Informed consent was obtained from all participants at enrollment in the Lund Stroke Register. The study was approved by the Lund Regional Ethics Committee.

### ***AF detection through electronic ECG archive***

AF documentation was based on ECG data obtained from the regional electronic ECG database (GE MUSE, GE Healthcare, MegaCare). The regional ECG database contains all ECGs taken in the hospital catchment area, including primary care facilities, starting from the year 1988. All available ECG recordings for all study subjects from 1988 until the end of follow-up in 2011 were reviewed by a trained cardiologist for presence of AF (MB). On surface ECG, AF was defined as a rhythm disorder with irregular RR intervals, indistinct P waves and atrial cycle length of < 200 ms where distinct atrial activity was visible on surface ECG (2). The first date of ECG with AF was considered to be the date of first ECG documentation of AF.

### ***AF detection by record linkage with national registers***

The Swedish Patient Register is administered by the Swedish National Board of Health and Welfare, and includes data on main and secondary diagnoses at discharge from all public



hospitals in Sweden starting in the year 1987. The Swedish Patient Register also includes information about outpatient visits to hospitals. All diagnoses are reported by physicians. The register uses International Classification of Disease (ICD) codes, with the 9<sup>th</sup> edition (ICD-9) used between 1987 and 1996, and the 10<sup>th</sup> edition (ICD-10) used from 1997 and until today (5, 9). For all study subjects, we searched for AF diagnosis by linking the subjects' personal identification numbers to the Swedish Patient Register, starting from 1987 and until the end of our follow-up in 2011. In our study, up to 13 secondary diagnoses were available for study subjects. AF was defined as presence of any of the following ICD codes: 427D for ICD-9 and I48 for ICD-10 (9).

Vital status, date of death, as well as primary and secondary diagnoses at death were determined via linkage with the Swedish Cause of Death Register for all study subjects. The Swedish Cause of Death Register is maintained by the Swedish National Board of Health and Welfare and contains information going back to 1961 and until present. The information is derived from death records, including underlying and up to 20 contributory causes of death coded to the current ICD edition at time of death. For our study population, ICD-10 was used (12, 13). Information was gathered starting from date of admission with ischemic stroke or enrolment in the study, and until the end of the 10-year follow-up. AF was defined as the presence of the I48 code from the ICD-10.

The first date corresponding to the AF code was considered to be the date of first AF documentation in the national registers.

### ***Case validation and statistical methods***

For all study subjects, we evaluated AF diagnosis using ECG data, data from the Swedish Patient Register, the Swedish Cause of Death Register up to the end of follow-up (October 17, 2011), as well as recorded information at index hospitalization with stroke or enrolment in the study. The

main survey was performed retrospectively on the entire study population based on information available by end of follow-up. In order to assess the impact of data availability for study subjects who died during the 10-year follow-up period (n=297), the analysis was repeated using ECG and the Swedish Patient Register data available at the time of inclusion in the study, when all patients and control subjects were alive. Additional subanalyses were performed in the stroke and control groups separately based on the information available by the end of follow-up in order to assess the accuracy of AF diagnosis in relation to the ischemic stroke history. A Chi-square test was used to compare categorical variables, and the non-parametric Mann-Whitney test was used for continuous variables. P-values were calculated using Fisher's exact test, with a two-tailed p-value < 0.05 being considered statistically significant.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for register-based AF diagnosis against ECG data, considered as the "gold standard" for AF verification.

All analyses were performed using SPSS Statistics 20 (SPSS Inc., Chicago, IL, USA).

## **Results**

A total of 7247 ECG recordings were available and reviewed for our study population: 3328 by inclusion in the Lund Stroke Register, and 3919 from date of inclusion to the end of follow-up. The median number of available ECGs per person was 7.5 (IQR 3-15) and was significantly higher among patients and controls with documented AF than among those without documented AF: 13 (IQR 8-23) vs. 6 (IQR 3-11),  $p < 0.001$ . The earliest AF documented by ECG was dated March 14, 1989 and the first AF diagnosis in the Swedish Patient Register was dated January 12, 1987.

Until the end of follow-up, AF by ECG could be detected in 190 study subjects, while 185 subjects had AF diagnosis in the Swedish Patient Register and 3 in Swedish Cause of Death Register only, thus bringing the total number of AF cases obtained from national registries to 188 (Figure 1). Due to the low number of AF cases obtained from the Swedish Cause of Death Register only and for the sake of brevity, we have in this report denoted the combined source of diagnostics information from the two national registries as “Swedish Patient Register” only. AF diagnosis by both ECG and Swedish Patient Register coincided in 152 subjects. In most cases (86%), AF was first documented by ECG. The median time from date of first AF on ECG to date of AF diagnosis in the Swedish Patient Register was 16 days (Table 1). In one-third of subjects with ECG-verified AF diagnosis, the time lapse between the dates of AF ECG documentation and diagnosis exceeded 6 months. AF was not detected by either ECG or the Swedish Patient Register in 446 individuals. Despite the high specificity of the Swedish Patient Register diagnosis, its sensitivity did not exceed 80%. PPV, specificity and sensitivity did not differ between stroke group and control group; however, NPV was lower in stroke patients (Figure 2, Table 2).

At inclusion in the Lund Stroke Register, as reported earlier (10), AF was documented by ECG in 122 study subjects, and by Swedish Patient Register in 118 subjects (Figure 1). AF diagnosis by both ECG and Swedish Patient Register coincided in 88 subjects, with ECG documentation of AF preceding the Swedish Patient Register diagnosis in most of them. The median time lapse between date of ECG documentation and the date of ICD code corresponding to AF being entered into the Swedish Patient Register was 10 days (Table 1). As in the main analysis, the time lapse between the first ECG-documented AF and Swedish Patient Register diagnosis exceeded 6 months for about one third of individuals. AF was not detected either by ECG or Swedish Patient Register in 520 subjects. Similarly to the analysis performed on the entire dataset at the end of the follow-up, analysis at inclusion in Lund Stroke Register showed high specificity but relatively low sensitivity of Swedish Patient Register diagnosis of AF (72%).

No difference was found between estimated values of AF diagnosis validity at inclusion and at the end of follow-up: the p-value for PPV was 0.196, for NPV it was 0.278, for sensitivity the p-value was 0.107, and for specificity it was 0.187.

## **Discussion**

We conducted a validation study of AF diagnosis recorded in the Swedish Patient Register using ECG documentation in the regional ECG database as a “gold standard”. By reviewing 7247 ECGs, we were able to validate not only the presence of ECG documentation for patients with AF diagnosis in the Swedish Patient Register, but also to assess the specificity and sensitivity of AF diagnosis – which, to the best of our knowledge, has not been reported earlier. One of our most important findings is that using Swedish Patient Register information to estimate the number of AF cases can result in underestimating the prevalence of AF by at least 20%, which corresponds to the number of subjects in our study who had ECG documentation of AF, yet no AF diagnosis in Swedish Patient Register.

To the best of our knowledge, our study is the first, in which validity of AF diagnosis in the Swedish Patient Register was assessed using direct ECG verification in a large unselected cohort of consecutively-enrolled patients, including subjects both with and without AF diagnosis, thus enabling the assessment of sensitivity and specificity of register-based AF diagnoses. In one recent study (14), Swedish Patient Register appeared to underestimate AF diagnosis in ischemic stroke patients by 23% when compared with information on AF diagnosed by primary care facilities. This further supports the importance of access to either ECG documentation or clinical information collected by primary care providers in order to assess the presence of AF in high-risk patient groups.

Only a small number of studies have addressed the AF diagnosis validation issue in other countries. In a recent Danish study, the PPV for AF diagnosis in the Danish National Patient Registry on a selected sample of 300 patients was reported to be 92% using a combination of ECG and medical record information (15). In our study, only ECG data were used to confirm AF, which explains why validity of AF diagnosis in the Swedish Patient Register (i.e. PPV) appeared to be lower than previously reported in studies based on combined information sources (9, 15, 16). However, in the Danish study (15), AF diagnosis was definitely confirmed by relevant documentation in only 229 of 284 patients (81%), which is in line with our findings.

In the present study, we report a lower PPV of register-based AF diagnosis than the 97% we previously reported (9). Two main reasons that may explain the difference between the two study results are that, in our previous study, AF diagnosis validation was performed in a randomly selected sample of 100 patients with a positive AF diagnosis by Swedish Patient Register, including a review of medical records – which was not done in the present study. However, even if only ECG verification was used, the PPV estimated in the present study is still lower than the 95% PPV from our earlier report. The difference may also be due to that the study population in our earlier study (9) was randomly selected from a prospective epidemiological cohort with a specific, standardized protocol for registration of their health status, and therefore, those study subjects may have been more thoroughly examined and may have more extensive medical documentation, including ECG recordings, than the patients enrolled in the Lund Stroke Register. It is also possible that patients included in the present study might have had ECG recordings showing AF, which were not properly archived and were unavailable for review thus leading to possible underestimation of the number of ECG-confirmed AF cases.

The sensitivity of AF diagnosis in the Swedish Patient Register was found to be 72% at the time of enrolment – this is in agreement with the 71% sensitivity previously reported in the Cardiovascular Health Study (16). At end of follow-up in our study, the sensitivity had increased to 80%, but the difference between the two estimates was not significant.

The sensitivity, specificity and PPV were similar between the stroke patients and the control subjects and were comparable with the data reported for the entire study population, which supports the reliability of these estimates. The only difference was found for NPV, which was lower in stroke population (89%), likely due to a higher prevalence of AF in the stroke patients than in the control subjects.

Despite the high NPV related to the relatively low prevalence of AF in the studied population, the sensitivity of AF diagnosis in the Swedish Patient Register appears to be rather modest, and indicates that the actual number of stroke patients with AF may be at least 20% higher than the number of patients assessed using only the Swedish Patient Register. The underestimation of AF in Swedish Patient Register can in part be explained by the fact that AF may have been considered as a comorbidity not necessarily present or requiring interventions at the time of hospital admission and for that reason not indicated as a diagnosis. Notably, in our study AF diagnosis validity appeared to be very similar at two measurements taken 10 years apart and based on nearly twice as many ECGs available for analysis at the end of follow-up as compared to the number of ECGs available at the time of the study subjects' inclusion in the Lund Stroke Register, which supports the reliability of our estimates. Also notable is that ECGs uploaded to the regional archive reflect predominantly symptomatic AF that leads to the patients' contact with healthcare providers – still, the true prevalence of AF in the overall population is likely underestimated. Dedicated AF screening, however, enables the detection of additional cases of asymptomatic or mildly symptomatic AF, as recent studies show (17-19).

In our study, we found that ECG diagnosis of AF preceded AF registration in the Swedish Patient Register in most patients, most likely since the first documentation of AF was made at the primary care level and not in the hospital. While electronic ECG archive covers both primary care facilities and in-hospital units, the Swedish Patient Registry only contains information on patients who were hospitalized, thus explaining the time lapse. In approximately one third of all cases, the time lapse between the date of the first ECG recording with AF to the date corresponding to AF code being entered in the Swedish Patient Register was longer than 6 months.

The time lapse in AF diagnosis, as described in our study, may result in a situation where the Swedish Patient Register does not provide complete information about AF prevalence at a certain point in time, thus decreasing register data reliability. Nevertheless, our study showed that the median time between ECG and Swedish Patient Register diagnosis usually did not exceed three weeks, which indicates that such a time lapse should not significantly affect validity of register data. Additional information from outpatient care providers may further improve validity of register-based identification of patients with AF.

### **Study Limitations**

Several issues need to be kept in mind when interpreting our findings. Stroke patients enrolled in the Lund Stroke Register were mostly treated at hospital, and so these patients likely had higher number of ECG recordings and discharge diagnoses recorded in the Swedish Patient Register than subjects recruited from general population. Although our study consisted of an unselected cohort of consecutively-enrolled patients, our study sample of patients with ischemic stroke and matched control subjects may not be representative of the population in general.

However, patients with ischemic stroke are individuals for whom knowledge about prevalent and incident AF is crucially important to assess risk and predict prognosis.

In this study we did not consider the type of AF (permanent or non-permanent). It is likely that permanent AF is easier to capture on ECG than non-permanent AF which may have affected AF detection rate in patients with different clinical types of AF. Underestimation of asymptomatic AF is another well-known problem, which is an inherent limitation for population-based studies where information on incident AF is obtained from diagnosis registers. The number of ECGs available for analysis in our study was lower for patients without AF documentation: this could be due to both lack of AF diagnosis and also due to those patients having better health status and thus lesser need to contact health care providers than patients with documented AF. Another limitation was that we were unable to monitor the subjects' mobility between various geographical regions, as our ECG search was limited to the ECG database that only covers Southern Sweden's Scania region – thus, ECG registrations possibly made in other regions of Sweden were unavailable for our review.

Although ambulatory ECG recordings taken at hospitals were also available for our review, we cannot claim that we could capture all ambulatory ECGs taken at the primary care level, which might also contribute to underestimation of the AF diagnosis specificity in the Swedish Patient Registry.

Finally, the ECG diagnosis was verified against snapshot 10-seconds long ECG recordings from electronic archive and we took for granted that the arrhythmia captured on a snapshot ECG should have lasted long enough to be considered as AF. However, this approach still leaves a possibility, even though rather unlikely, that the duration of AF episode did not reach 30 seconds required for diagnosis as per current recommendations (2).



## **Conclusion**

Despite high specificity and NPV, diagnosis of AF in the Swedish Patient Register has modest sensitivity, which may result in underestimating prevalent and incident AF cases by at least 20% if only register-based information is used to identify subjects with AF in epidemiology studies. A time lapse of more than 6 months for AF registration in the Swedish Patient Register after the first ECG documentation was noted for a significant minority of patients (one-third), and should be considered when interpreting AF prevalence and incidence estimates using only register data.

## **Conflict of interests**

None of the authors has any competing interests.

## **Funding and acknowledgements**

This work was supported by the Swedish National Health Service, Skåne University Hospital, Lund, Sweden, the Swedish Heart-Lung Foundation, the Swedish Research Council (K2010-61X-20378-04-3), Region Skåne, the Freemasons Lodge of Instruction EOS in Lund, King Gustaf V and Queen Victoria's Foundation, Lund University, and the Swedish Stroke Association.

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**Table 1.** Time lapse between ECG and documentation of atrial fibrillation (AF) in the Swedish Patient Register.

Variable	At enrolment in the study			At the end of FU		
	Total, n=88	Stroke patients, n=70	Controls, n=18	Total, n=152	Stroke patients, n=104	Controls, n=48
First AF documentation by ECG, n (%)	72 (82)	61 (87)	11 (61)	131 (86)	94 (90)	37 (77)
Time lapse between ECG and register diagnosis exceeding 6 months, n (%)	26 (30)	24 (34)	2 (11)	51 (34)	38 (36)	13 (27)
Median time from AF ECG to register diagnosis, days (IQR 25%-75%)	10 (1-335)	16 (5-964)	1 (0-6)	16 (3-859)	35 (6-1277)	6 (1-209)

AF – atrial fibrillation; IQR – interquartile range; FU – follow up. Enrolment of subjects was performed in 2001-2002 and the follow-up in 2011.

**Table 2.** Comparison of positive predictive value (PPV), negative predictive value (NPV), sensitivity and specificity of atrial fibrillation diagnosis in Swedish Patient Register between stroke patients and control subjects by the end of follow-up.

	All patients, n=672	Stroke group, n=336	Control group, n=336	P-value
PPV, %	81	85	74	0.076
NPV, %	92	89	95	0.033
Sensitivity, %	80	82	76	0.355
Specificity, %	93	91	94	0.236

**Figure 1.** Positive predictive value (PPV), negative predictive value (NPV), specificity and sensitivity of AF diagnosis obtained from the Swedish Patient Register compared with ECG documentation in the whole study population.

**Figure 2.** Positive predictive value (PPV), negative predictive value (NPV), specificity and sensitivity of AF diagnosis obtained from the Swedish Patient Register compared with ECG documentation in the stroke group and in the control group.

At enrolment  
in the Lund Stroke Register

		AF by ECG		
		AF	No AF	
AF by register	AF	88	30	PPV 75%
	No AF	34	520	NPV 94%
		Sensitivity 72%	Specificity 95%	

At end of follow-up

		AF by ECG		
		AF	No AF	
AF by register	AF	152	36	PPV 81%
	No AF	38	446	NPV 92%
		Sensitivity 80%	Specificity 93%	

At end of follow-up  
in the stroke group

		AF by ECG		
		AF	No AF	
AF by register	AF	104	19	PPV 85%
	No AF	23	190	NPV 89%
		Sensitivity 82%	Specificity 91%	

At end of follow-up  
in the control group

		AF by ECG		
		AF	No AF	
AF by register	AF	48	17	PPV 74%
	No AF	15	256	NPV 94%
		Sensitivity 76%	Specificity 94%	