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RESEARCH ARTICLE

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Antiepileptic medicines in men and women with stroke in Sweden, a registry-based study

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Abstract

Background and aim: To describe the utilization of the first antiepileptic drug (AED) in men and women with previous stroke in a nationwide population.

Methods: Prescription data, patient's age, and sex were collected from the Swedish Drug Register and cross-linked to diagnosis data from the National Patient Register and data from Statistics Sweden. Patients with a first dispensation of an AED after stroke between 1 January 2007 and 31 December 2014 were included.

Results: A total of 10 958 patients with stroke were initiated on AED treatment (51% women, mean age 75 years). Gabapentin (n = 3073, 28%), pregabalin (n = 2476, 22%), carbamazepine (n = 2330, 21%), levetiracetam (n = 1158, 10%), and valproic acid (n = 833, 7%) were the most dispensed AEDs. After stratification by the presence of a neuropathic pain diagnosis, gabapentin, and pregabalin were the most used AEDs. In contrast, after stratification for epilepsy/convulsions diagnosis, carbamazepine and levetiracetam were the most initiated AEDs.

Conclusion: This study suggests that AED is mainly used for neuropathic/poststroke pain and the study shows gabapentin and pregabalin to be the most used AEDs. For epilepsy, carbamazepine and levetiracetam were the most used AEDs in patients with previous stroke.

KEYWORDS
antiepileptic drugs, poststroke epilepsy, sex differences

1 | INTRODUCTION

Antiepileptic drugs (AEDs) can be used after stroke for different reasons. Stroke is a common cause of epilepsy in adults and elderly in Europe.[1] Estimates show that 2%-14% of all patients who have had a stroke develop epilepsy, most within 2 years of stroke onset.[2,3] Poststroke seizures are divided into early-onset (within 7 days after stroke) and late-onset (more than 7 days after stroke). After a first unprovoked late-onset seizure, there is a high risk of recurrence and pharmacological treatment is motivated.[2] Seizures after stroke can worsen long-term functional outcomes and increase mortality. However, few randomized controlled trials have evaluated antiepileptic treatment specifically in poststroke epilepsy (PSE)[4] and it is uncertain whether some AEDs have superior effect or tolerability in PSE.

Choice of AED in epilepsy is based on seizure type and patient factors such as age, sex, other drug treatments, comorbidities, and the drug's adverse effect profile.[5] Consideration to pharmacokinetic drug-drug interactions between AED and other pharmacological treatment is particularly challenging in the treatment of elderly and those with numerous comorbid conditions. Drug of choice for

antiepileptic treatment after stroke has traditionally been carbamazepine but newer AEDs, such as levetiracetam and lamotrigine and in the elderly also gabapentin, are recommended as first-line treatment.[6]

In patients with a former stroke, neuropathic pain is not uncommon and may present months after the stroke. A large prospective study found 2.7% of stroke patients to develop central pain within 1 year of the stroke.[7] Even though the evidence of effect is weak, both AED and antidepressive drugs are commonly used.[7] For lamotrigine, however, a meta-analysis demonstrated a positive effect in poststroke neuralgia.[8]

Other indications for AEDs are bipolar disease (valproic acid and lamotrigine), general anxiety disorder (pregabalin, tiagabine, and valproic acid),[9] and migraine prevention. Migraine is common in the general population and has been estimated at a prevalence in adults of 15%.[10] There is an increased risk of stroke in patients with migraine.[11] Also, migraine and epilepsy may be comorbid conditions.[12] The most commonly used AEDs for migraine prevention are topiramate and valproic acid.[13]

There is limited knowledge about to which extent AEDs are used in patients with previous stroke in Sweden, on which indications, which AEDs are used, and if there are sex differences. The aim of this study was to analyze initiations of AEDs in men and women with previous stroke in Sweden.

2 | MATERIALS AND METHODS

2.1 | Study design

This nationwide study is a cross-sectional study with data obtained from cross-linked national health registers in Sweden. Information on dispensed prescription medications (as well as the patient's sex and age) was collected from the Swedish Drug Register.[14] This register, established in July 2005, has almost complete coverage of dispensed prescriptions in Sweden. Information on patient's diagnoses was obtained from the National Patient Register and identified using ICD-10 codes.[15] This register contains information on all healthcare visits in inpatient and specialized outpatient care. Information on country of birth was collected from Statistics Sweden (SCB).[16] Individual prescription data were linked with specific diagnoses by using the personal identification number assigned to each Swedish resident.[17]

2.2 | Study population

From the Swedish Drug Register, we retrieved data of all adult patients (≥18 years) in Sweden with a first dispensed prescription of an AED (ATC code beginning with N03A) between 1 January 2007 and 31 December 2014. All AEDs available in Sweden were included in the analysis. First, the dispensation of AED was defined as not having any dispensation of an AED with the same unique ATC code in the previous 12 months (wash-out period 1 year). We only included patients with a stroke diagnosis recorded in the National Patient Register up to 2 years prior to their first AED claim.

All stroke types were included and divided into subgroups; subarachnoid hemorrhage (SAH) (ICD-10 code I60 and possibly I69), intracerebral hemorrhage (ICD-10 code I61 and possibly I69), ischemic stroke (ICD-10 code I63 and possibly I69), and a mixed group (ICD-10 codes I60 or I61 or I63 or I64 or I69).

2.3 | Presence of comorbidities

Information on the presence of an epilepsy diagnosis or other relevant diagnoses in the study population was also added. These diagnoses were identified according to ICD-10 codes and had to be recorded within the same time window as for the stroke diagnosis, that is, 2 years prior to the date of the first dispensed AED prescription. The selected diagnoses reflect the officially approved indications for AEDs in Sweden (Table 1). An indication hierarchy was used, including (a) epilepsy or unspecified convulsions; (b) neuropathic pain disorder; (c) psychiatric disorder; (d) migraine; and (e) other diagnoses.

2.4 | Statistical analyses

Yearly incidences of AED use (cumulative incidence) were calculated for each calendar year during the study period from 2007 to 2014, divided for each stroke type and for men and women.

2.5 | Ethical approval

The study was approved by the Regional Ethical Review Board in Stockholm, Sweden (Ethical Approval Number 2015/660-31 and 2019/03564).

TABLE 1 Diagnoses analyzed in the study population according to a hierarchy of recorded diagnoses in register

	Diagnoses in the indication hierarchy	ICD-10 codes	No recorded diagnosis of
I	Epilepsy or convulsions	G40-41, R25, R56	
II	Neuropathic pain	G50-59, G60-64, M79, G82, G95, G97.9, M50-54, M89, R20, R51-52, Z03.3	I
III	Psychiatric disorder	F30-39, F40-48, F10, F55, F50, F60	I-II
IV	Migraine	G43-44	I-III
V	Other diagnoses		I-IV

3 | RESULTS

3.1 | Study population

During the study period, there were in total 469 681 first claims of an AED. Of these, 11 134 first claims were made in 10 958 unique patients with a stroke diagnosis (51% women) and therefore included in the analysis. Most patients were between 70 and 89 years of age at the time of their first AED dispensation. Women were in average older than men in all stroke type (Table 2).

Overall, ischemic stroke was the most common stroke type registered in patients initiated on AEDs. A diagnosis of ischemic stroke or SAH was more common in women, while ICH was more common in men (Table 2). About a third of the study population (34.6%) also had a diagnosis of epilepsy or convulsions registered within the 2 years prior to the first AED dispensation (Table 2). Of persons in the study population with no epilepsy diagnosis, neuropathic pain was registered in 24.1%, a psychiatric disorder in 6.4%, and migraine in 0.4%.

3.2 | Utilization of antiepileptic drugs

Of the 11 134 first claims of AEDs in stroke patients, 3073 were gabapentin (28%), 2476 were pregabalin (22%), 2330 were carbamazepine (21%), 1158 were levetiracetam (10%), and 833 were valproic acid (7%).

Users of gabapentin and pregabalin were more likely to be women (Figure 1) and in the age group 80 years and older. Among users of gabapentin, 40% of the men and 38% of the women had a registered diagnosis of neuropathic pain. However, 49% of the men and 52% of women with gabapentin had no diagnoses of either epilepsy/convulsions, psychiatric disorder, or neuropathic pain. Among users of pregabalin, 39% of the men and 41% of the women had a neuropathic pain diagnosis, but 46% of the men and 46% of the women had no diagnoses of either epilepsy/convulsions, psychiatric disorder, or neuropathic pain.

The total number of AED initiations increased during the study period. Largest increases were seen for gabapentin and levetiracetam, in both men and women.

TABLE 2 Characteristics of the study population, in all 10 958 persons having 11 134 dispensations

	AED dispensation in men (n = 5439)	AED dispensation in women (n = 5695)	Total dispensations (n = 11 134)
	n (%)	n (%)	n (%)
Stroke types (ICD-10 code)			
Subarachnoid hemorrhage (I60)	153 (48.1)	165 (51.9)	318
Intracerebral hemorrhage (I61)	520 (54.7)	431 (45.3)	951
Cerebral infarction (I63)	2501 (46.4)	2884 (53.6)	5385
Stroke not specified as hemorrhage or infarction (I64)	203 (46.1)	237 (53.9)	440
Sequelae of cerebrovascular disease (I69)	1782 (51.4)	1682 (48.6)	3464
Age groups			
18-64	1360 (25.0)	907 (15.9)	2267 (20.4)
65-79	2302 (42.3)	1772 (31.1)	4074 (36.6)
80+	1777 (32.7)	3016 (53.0)	4793 (43.0)
Mean age (years)	72.1	77.0	74.6
Country of birth			
Sweden	4730 (87.0)	4913 (86.3)	9643 (86.6)
Europe	553 (10.2)	632 (11.1)	1185 (10.6)
Outside Europe	156 (2.9)	150 (2.6)	306 (2.7)
Comorbidities			
Epilepsy/convulsions	2009 (36.9)	1838 (32.3)	3847 (34.6)
Neuropathic pain	1236 (22.7)	1451 (25.5)	2687 (24.1)
Psychiatric disorder	367 (6.7)	346 (6.1)	713 (6.4)
Migraine	17 (0.3)	30 (0.5)	47 (0.4)
Other diagnoses	1810 (33.3)	2030 (35.6)	3887 (34.5)

Note: Inclusion criteria for the study population were age ≥ 18 years, a stroke diagnosis recorded in the National Patient Register up to 2 years before the first AED claim, and a dispensation of an AED (ATC code beginning with N03A) between 1 January 2007 and 31 December 2014.

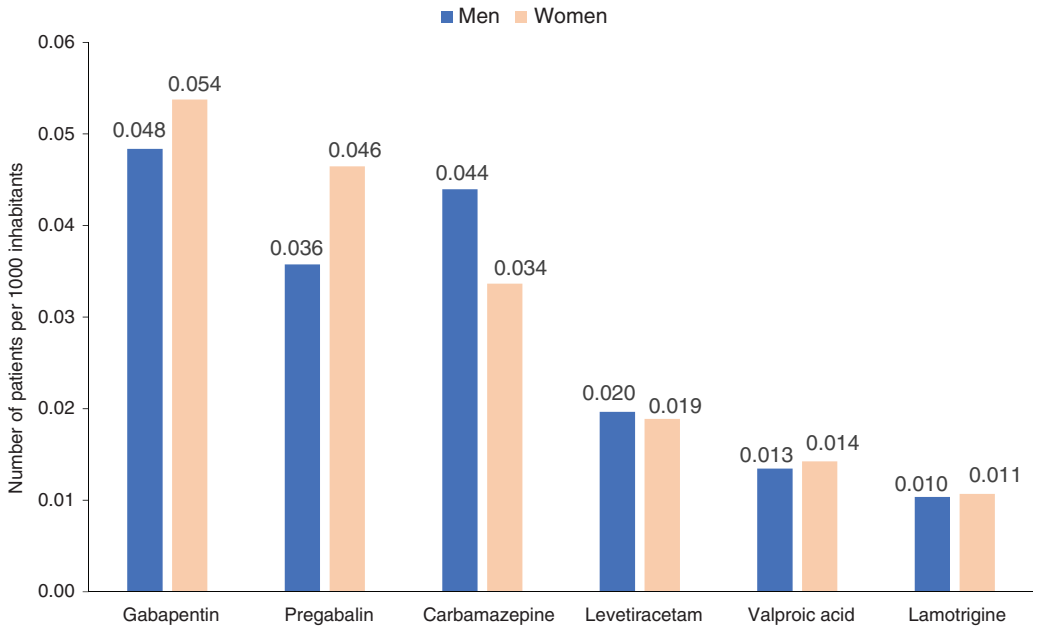

FIGURE 1 The most utilized antiepileptic drugs in men and women with a stroke diagnosis

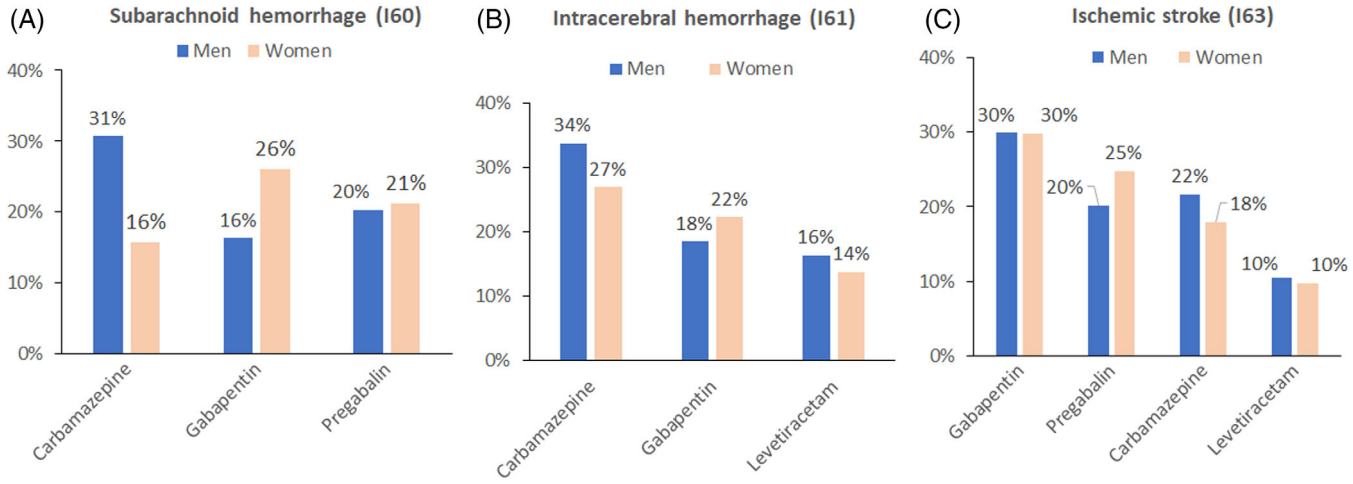

FIGURE 2 Utilization of the most common antiepileptic drugs divided by patient's sex and stroke subtype; subarachnoid hemorrhage (A), intracerebral hemorrhage (B), and ischemic stroke (C), 2007-2014

3.2.1 | Utilization in patients with ischemic stroke

Women with previous ischemic stroke had higher incidence use of AED than men (0.095 vs 0.084 PAT/TIN). Gabapentin was most common in both men and women, followed by pregabalin in women and carbamazepine in men (Figure 2C).

3.2.2 | Utilization in patients with intracerebral hemorrhage

Men with previous intracerebral hemorrhage had higher incidence use of AED than women (0.017 vs 0.014 PAT/TIN). Carbamazepine was most common in both men and women, followed by levetiracetam (Figure 2B).

3.2.3 | Utilization in patients with subarachnoid hemorrhage

Women had higher incidence use than men (0.054 vs 0.051 PAT/TIN). Carbamazepine was most common in men, whereas gabapentin was most common in women (Figure 2A).

3.2.4 | Utilization with presence of comorbidities

Stratification by the presence of relevant diagnoses changed the utilization pattern, and some sex differences disappeared. After stratification for a diagnosis of epilepsy/convulsions, carbamazepine appeared to be the most initiated AED in men and women for all stroke

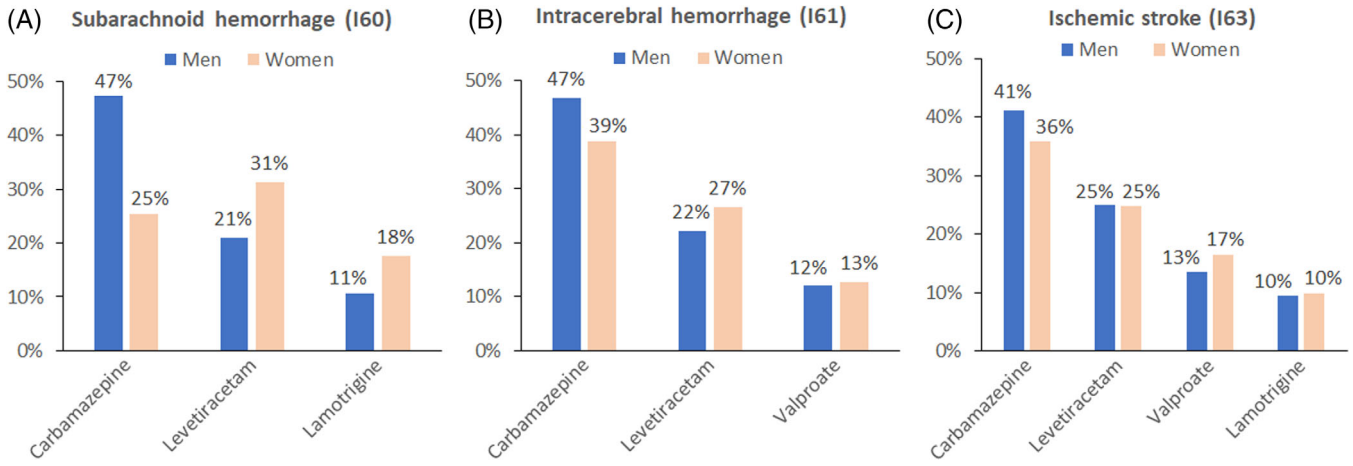

FIGURE 3 Utilization of the most common antiepileptic drugs in epilepsy/convulsions, divided by patient's sex and stroke subtype; subarachnoid hemorrhage (A), intracerebral hemorrhage (B), and ischemic stroke (C), 2007-2014

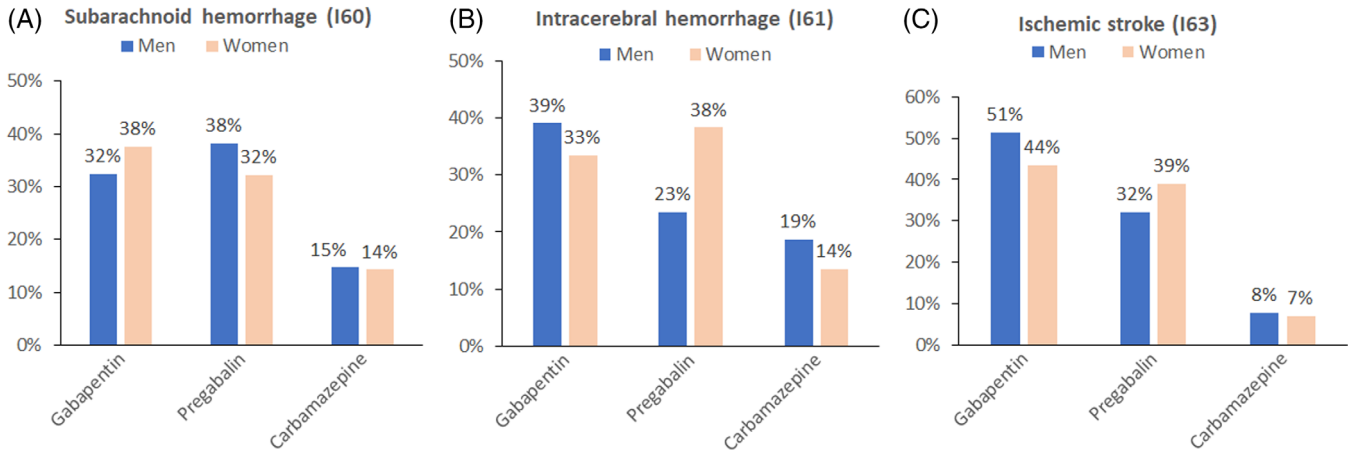

FIGURE 4 Utilization of the most common antiepileptic drugs in neuropathic pain disorders, divided by patient's sex and stroke subtype; subarachnoid hemorrhage (A), intracerebral hemorrhage (B), and ischemic stroke (C), 2007-2014

subtypes, except for women with SAH who were most likely to be initiated on levetiracetam (Figure 3).

In patients with a diagnosis of neuropathic pain, gabapentin and pregabalin were the mainly initiated AEDs in men and women, regardless of stroke subtype (Figure 4). In women, gabapentin was most common in SAH and ischemic stroke, whereas pregabalin was most common in ICH. In men, gabapentin was the most common irrespective of stroke subtype.

In patients with a diagnosis of psychiatric disorder, carbamazepine and pregabalin were the mainly initiated AEDs for all stroke subtypes. Carbamazepine was the most common in both men and women with ICH (25% and 28%, respectively) and in men with SAH (38%). Pregabalin was most common in both men and women with ischemic stroke (35% and 41%). Men with SAH were mainly initiated on carbamazepine, whereas women with SAH were mainly initiated on pregabalin (38% and 56%, respectively). However, the numbers of patients with a diagnosis of psychiatric disorder were very few (ischemic stroke n = 331, ICH n = 65, SAH n = 25).

4 | DISCUSSION

Indication for AED use in patients with a previous stroke vary. This study show epilepsy to be most often registered (in 35% of patients) followed by neuropathic pain (in 24% of patients) and psychiatric comorbidity (6% of the patients). However, in almost one-third of the patients, none of the common indications for AEDs were registered.

Gabapentin, pregabalin, and carbamazepine were the most dispensed AEDs, together making up almost three-quarters of all AED dispensation. While gabapentin and carbamazepine can be used for different indications, pregabalin is mainly used in neuropathic pain. The evidence for pregabalin use in central neuropathic pain, such as poststroke pain, is limited and a recent meta-analysis described it as inadequate.[18] Pregabalin is not indicated as monotherapy in epilepsy as the evidence of effect is as an add-on only.[19,20] As the present study analyses first dispensation of AED (ie, incident treatment), we interpret virtually all pregabalin to be on the indications neuropathic pain or generalized anxiety syndrome.[20] Gabapentin, the most

commonly dispensed AED, has indications for both neuropathic pain and epileptic seizures.[21] Carbamazepine, on the other hand, is used in epilepsy with focal onset, generalized seizures, and mixed types and in addition to that trigeminal neuralgia.[22,23] Levetiracetam, while effective in epilepsy, has not been shown to be effective in neuropathic pain.[23,24]

The high use of gabapentin and pregabalin in this study population could be explained by their use for poststroke pain. In a prospective study, 2.7% of stroke patients developed central poststroke pain, but other studies report up to 35% of patients with stroke develop central poststroke pain.[25] When we stratified AED use by the presence of a neuropathic pain diagnosis, the proportion initiated on gabapentin or pregabalin increased and these two constituted the mainly initiated AEDs. In contrast, after stratification for epilepsy/convulsions diagnosis, the proportions of gabapentin and pregabalin diminished dramatically, and carbamazepine and levetiracetam constituted the most initiated AEDs. This is in line with present evidence. Both carbamazepine and levetiracetam are first-line treatments for focal onset seizures. As the risk of recurrence after first time late-onset seizure (>7 days) after stroke is high, up to 71% over 10 years, AED treatment is usually started immediately after first seizure post-stroke.[4] The risk of early recurrence might explain why lamotrigine is used less than in other types of focal onset epilepsy. Reaching an efficient dose of lamotrigine is slow as the medication needs to be introduced gradually due to the risk of developing cutaneous side effects and thus may not the first choice.[26] This, despite that studies indirectly indicate a similar efficacy between levetiracetam, carbamazepine, and lamotrigine, whereas the risk of adverse events has been shown to be higher for carbamazepine compared with lamotrigine and levetiracetam.[4]

There is yet no conclusive data on which AED to choose in PSE. The mean age of the patients is rather high, and comorbidity and co-medications need to be considered when choosing an AED. Even though carbamazepine, an enzyme inducer and QT-prolonging drug, is the most commonly first AED in this cohort. However, the data are not updated since 2014. Another Swedish study on PSE treatment 2005-2010 found carbamazepine to be the most used AED during the entire time, but levetiracetam to be increased over time to become the most common first choice in the end of the study period.[27] More studies on the efficacy, effect, and risk of adverse effects need to be performed in patients with poststroke complications such as seizures and central pain.

The strength of this study is the use of population data that can be linked by using the unique personal identification numbers each Swedish inhabitant has.[17] The Swedish Drug Register has excellent coverage of all drugs dispensed to Swedish inhabitants and only excludes drugs used during hospital stay or residents in the few nursing homes with medical supply.[14] As in all registry-based studies, the validity of the diagnoses is a possible limitation. However, the sensitivity of the National Patient Register for a correct stroke diagnosis has been estimated to be good, 83%-94%.[28,29] Similarly high validity, around 90%, has been shown for an epilepsy diagnosis (G40),[30] The main limitation with the Swedish Drug Register is the lack of information on the underlying clinical diagnosis for the dispensed drugs. As the National Patient Register does not include primary care diagnoses and most patients with stroke are followed long term in Primary Care, indications cannot be retrieved from the present data. Another limitation with our study is the length of the wash-out period. A wash-out period of 1 year was considered appropriate for identifying incident treatment with AED in patients with epilepsy. However, it is possible that some patients had switched between different AEDs throughout the study period and therefore have several dispensations.

With gabapentin and pregabalin being the most used AEDs, this study suggests that AED is mainly used for neuropathic/poststroke pain. For PSE, carbamazepine and levetiracetam were the most common first choice of AEDs.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

AUTHOR CONTRIBUTIONS

Conceptualization: Mia von Euler
Formal Analysis: Linnéa Karlsson Lind
Funding Acquisition: Mia von Euler
Methodology: Mia von Euler, Linnéa Karlsson Lind
Supervision: Mia von Euler
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Writing – Review and Editing: Mia von Euler, Linnéa Karlsson Lind

All authors have read and approved the final version of the manuscript.

Mia von Euler and Linnéa Karlsson Lind had full access to all the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

TRANSPARENCY STATEMENT

The corresponding author (Mia von Euler) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request and in accordance with Swedish legal regulations.

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