



## Socioeconomic evaluation of vagus stimulation: A controlled national study



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### ABSTRACT

**Purpose:** We aimed to determine the health costs and social outcomes in terms of education, employment and income level after insertion of a vagus nerve stimulator (VNS) in patients with epilepsy. **Methods:** This is a case–control study using Danish health care and socioeconomic register data. The analysis of the effect involved a comparison of the health care costs, occupation and income status of VNS-treated epilepsy patients with those of a control group of epilepsy patients who had a VNS implanted during the 12 months before the index date (pre-period) and during the two years after the index date (post-period).

**Results:** 101 patients who had undergone VNS implantation and 390 control patients were included. VNS implantation was associated with fewer inpatient admissions and emergency room visits and less frequent use of prescription medication compared with epilepsy patients without VNS implantation. VNS implantation was not associated with changes in occupational status (including employment and income). In fact, the number of people on disability pension increased during the period.

**Conclusions:** VNS implantation in people with epilepsy is associated with reduced health care use, but not with occupational or social status.

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### 1. Introduction

Epilepsy is a serious and chronic neurological disorder that affects all ages from childhood to old age [1]. Epilepsy in adults, children and adolescents is strongly associated with significant morbidities, mortality, stigma and reduced quality of life. It is also associated with educational and professional problems and may therefore have a substantial socioeconomic impact [2,3]. Despite decades of research focusing on its medical or surgical treatment, a significant proportion of patients are left with medically intractable epilepsy and continued seizures. Vagus nerve stimulation (VNS) has been provided to some of these patients, particularly those with the most severe conditions. VNS is an additive

treatment that may reduce seizure frequency and severity in patients with medically intractable epilepsy [4–6]. However, surgical implantation of VNS may cause complications and the VNS may cause side effects. The cost associated with its implantation may also limit the number of patients who are potentially treatable with the device. Little is known about the social outcomes of VNS implantation, but it is debatable whether VNS in general has an additive positive effect compared with the best available drug treatment [7]. Other studies have shown a positive effect, as determined by measures of pre- and post-VNS-implantation costs [8–13], although they did not compare these findings with a control group, or evaluate the social impacts of, for example, education and employment. Data on the consequences of VNS implantation are limited so we aimed to derive a national estimate of the effects of VNS implantation in persons with epilepsy on health care use and social outcomes compared with those in a control group who had not received a VNS implantation. We recently described the direct and indirect costs in children and adult patients diagnosed with epilepsy in Denmark [3]. These findings suggested that epilepsy causes a substantial health care

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burden not only at the time of diagnosis and after, but also before diagnosis. In this study, we focus on the health care costs and social outcomes for epilepsy patients undergoing VNS implantation based on a consideration of the national population.

## 2. Methods

In Denmark, it is possible to identify subjects with epilepsy, and to trace health, and educational, professional and income levels and thereby calculate direct and indirect costs related to diseases because information from general medical practice, and public and private hospitals, and the social and educational status of all Danes are registered in central databases that are linked by a unique identification number. We took advantage of historical medical archives of patients hospitalized with epilepsy in Denmark since 1997 [3], a randomly age- and gender-matched control group from the background population and several nationwide registers, including detailed information about education, employment, welfare benefits, family conditions, hospital contacts, visits to general practitioners and use of medication for the total Danish population. Using these data enabled us to identify long-term health and social effects before and after VNS implantation.

The study uses Danish health care and socioeconomic register data. The analysis of the effects involved comparing the health care costs, occupation and income status of VNS-treated epilepsy patients with those of a control group. We undertook a case-control study in which we compared the case study group (VNS implantation) and a control group (persons diagnosed with epilepsy who had no VNS implantation and no epilepsy surgery) during the 12 months before the index date (pre-period) and the two years following the index date (post-period).

We used the following national registers:

- The National Patient Registry (NPR) (Landspatientregisteret), which includes administrative information, diagnoses, and diagnostic and treatment procedures using several international classification systems, including the International Classification of Disorders (ICD-10). Since 1995, the NPR has also held information about outpatient costs.
- The Danish Prescription Register (Lægemiddelstatistik registeret), which includes information about usage and cost of medications.
- The National Health Insurance Register (Sygesikringsregisteret), which contains all contacts and costs in the primary sector (general practice and specialist care in the primary sector).
- The National Registers (Statistics Denmark), which include information about income from employment and public transfers.

### 2.1. Study population

The study examined only patients diagnosed with epilepsy (ICD-10: G40x; status epilepticus: G41x).

The follow-up population included VNS patients and their controls who were alive two years after VNS implantation (the index date).

### 2.2. Case group

The VNS case group consisted of all epilepsy patients receiving VNS who had not undergone an epilepsy surgery operation during the study period (i.e., between one year before and two years after the index date). A VNS patient was identified the first time the patient had a VNS procedure code registered in the NPR. Patients

receiving both VNS and epilepsy surgery (KAAJ) in the period were excluded from the study.

### 2.3. Control group

The control group consisted of patients with a diagnosis of epilepsy or status epilepticus and who had not undergone epilepsy surgery or VNS implantation. We matched the control group with respect to gender, year of epilepsy diagnosis, year of VNS implantation (index year), and age at time of VNS implantation.

Matching for the VNS stimulation year and the year of epilepsy diagnosis ensures that the control patients were alive at the time of VNS implantation.

Patients or controls who immigrated into or emigrated out of the country during the study period were excluded.

### 2.4. Health care costs

Health care costs were calculated as annual costs over the 12 months before the index date and during the two years after the index date.

Health care costs were calculated as totals based on costs of outpatient, inpatient, and emergency room visits, medicine, and primary health sector care. We estimated the indirect and direct costs related to epilepsy. All costs accruing from the epilepsy diagnosis and epilepsy medication costs were included in the epilepsy-related cost calculation.

In the analyses, only patients who were eligible for the whole period were included. If a patient or a control individual died during the post-period they were excluded from the cost calculation. This prevented the possibility of overestimating the effect due to the lower costs for dead patients and controls.

### 2.5. Income

Calendar year income is a stock variable, so we cannot follow a patient's income before and after the index date in the same way we are able to with the health care costs. Therefore, the pre-period income in the income analysis was taken as the calendar year before the index year, and post-income was the income two years after the index year. Patients younger than 18 years of age at the time of VNS implantation were excluded from the income calculation, because no children (those aged 15 years or younger) and very few patients under the age of 18 have income information. Of the total population of epilepsy patients who had undergone VNS surgery, 43% were under 18 years of age in the pre-VNS implantation period. Costs and income were considered in euros, adjusted to 2015 prices.

### 2.6. Occupation

Occupation was estimated in the November of the year before the index year and of subsequent years. The significance of the difference in occupational status between cases and controls was tested using a chi-square test.

## 3. Results

We included a total of 101 patients who had undergone VNS implantation and 390 control patients. One additional patient underwent VNS but died within the observational period and was excluded from this analysis.

The descriptive data are summarized in Table 1. Variables that were not matched were tested for significant differences using the chi-square test for count variables and the *t*-test for continuous variables. Due to the small number of observations compared with

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