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A study of the impact of VNS on health care utilisation in England

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ABSTRACT

Purpose: To compare hospital service use before and after VNS therapy implantation in a sample of drug-resistant people with epilepsy.
Method: The before and after study was performed using anonymised Hospital Episode Statistics (HES) data from one year before to 3 years after implantation in 321 patients from data collected between April 2009 to July 2011. Episodes relating to out-patient clinic, Accident and Emergency (A&E) department attendance, hospital admissions and length of stay were collected and compared. Descriptive statistics are used to summarise patient demographics, patient pathways and resource usage before and after VNS implantation. Means and proportions were reported on continuous variables, proportion and frequency on categorical variables. Trends of activity over time were determined using before and after VNS comparisons and tested with the Wilcoxon Signed-rank (WSR) test.
Results: The summary statistics indicate a drop in resource use in terms of in-patient bed-days (21% decrease), elective in-patient episodes (7% decrease) and non-elective in-patient episodes (14% decrease). There was an increase in the quarterly average out-patient appointments by 12%. The A&E attendance outcome recorded a mean increase in quarterly attendances of 9% but a slight decrease when subject to a signed rank test. These contradictory results should therefore be treated with caution.
Conclusion: VNS Therapy may be associated with an overall reduction in health service resource use.

1. Introduction

Patients with drug resistant epilepsy (DRE) may be referred to an Epilepsy Surgery Programme but some are not suitable for resective surgery for their epilepsy [1–3]. This is due to a number of factors including poor localisation of lesions, the location of seizures, and co-morbidities [4]. The palliative procedures available for such cases include corpus callosotomy, stimulation of the vagus nerve, deep brain stimulation and transcranial magnetic stimulation. Of these palliative procedures Vagus Nerve Stimulation (VNS Therapy®, Cyberonics Inc. Houston TX, USA) has gained widespread popularity and in excess of 80,000 devices world-wide have been implanted in DRE patients in the last 20 years. Vagus nerve stimulation (VNS) can reduce seizures in some patients with DRE [5] and yet there is a variable referral rate for assessment for VNS therapy.

The pattern of under-referral is reported internationally with referral for surgical assessment in Sweden estimated to be underused in individuals with focal drug resistant epilepsy [6]. In the USA trends in lobectomy between 1990 and 2008 suggests underutilisation despite a doubling in hospitalisations in that period for DRE [7]. A retrospective study suggests that referral may be increasing in line with recommendations from the American Academy of Neurology (AAN) [8]. A survey of neurologists in the UK highlighted an overall reduction of adult surgical treatments from a total of 578 in 2000 to 472 in 2011. There was an almost 50% drop in lesional resection with an increase in neuromodulatory procedures from 156 to 230 [9]. In children the picture may be different with a single centre study from Holland showing an increase in resective surgery each year from 1990 to 2011 [10].

The pattern of VNS use in England is interesting in that while the number of resective surgery procedures fell in the first decade

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of this century, the numbers of VNS implantations in the UK in adults increased [9]. VNS now accounts for over half of epilepsy surgery procedures (55.2%) of which 69% were performed in 6 large university centres [9]. In England and Wales VNS implantation has risen from 148 new implants in 2009 to 246 in 2013 with some centres implanting over 50 devices in this period and some less than 10 devices. There was also an associated increase in battery replacements with 81 in 2009 and 302 in 2013. This is in line with guidance in the UK [11] that recommend VNS as a treatment for both focal and generalised seizures in children and adults. In the USA guidance recommends consideration of VNS for Lennox Gaustaut Syndrome (LGS) because the responder rates for patients with LGS appears not to differ from the general population of patients with drug resistant epilepsy [12].

The factors affecting the variable referral rate for VNS assessment are not known. Clearly, the therapy is effective in the majority of recipients although some patients do not respond [5,13,14] but treatment costs may be a factor.

The costs of assessment and implantation are significant but in the USA, the device costs are balanced by a reduction in health care utilisation costs with the breakeven point being after 18 months of therapy overall but with a more rapid break-even point of 12 months for 12–18 year olds [15,16]. It is not clear whether this picture would transfer from the American mixed model health system where health expenditure costs 16.9% of GDP in 2010 to the UK system where there is a cost contained single tier taxation based Beveridge health system [17] costing 9.3% of GDP [18].

With the increasing use of VNS Therapy in the UK, It is also timely to explore the clinical impact of VNS given the relationship of seizure frequency to hospital utilisation [19] and the evidence relating to seizure reduction with VNS Therapy [7,15,20]. The NHS Commissioning Board, recognising that 'patients with refractory epilepsy require more out-patient clinic time, combination therapy (often with newer, expensive anti-epileptic drugs) and hospitalisation' developed a commissioning policy for VNS to ensure more equitable provision of services [21]. This policy should be welcomed by commissioners who are aware of the increasing burden of non-elective activity on the NHS [22–24] reported by NHS England as 5.9% more episodes of unscheduled care in 2012–2013, than in 2009–2010; an increased number of acute admissions putting pressure on bed occupancy with 10.6% more emergency admissions in 2012–2013 than in 2009–2010 [25] and a reported 12% increase in Accident and Emergency (A&E) attendance in the last decade [26]. This study assessed the effect of VNS Therapy on hospital utilisation.

2. Methods

A before and after health utilisation study was performed on 321 anonymised patients who received VNS Therapy in NHS hospitals in the UK between April 2009 and July 2011 of which nearly half ($n = 123$) were implanted in 3 centres (Bristol, Kings College London and Sheffield).

Hospital Episode Statistics (HES) data of elective and non-elective in-patient admissions and out-patient appointments and also A&E department attendances and disposal were analysed in the secondary care setting, activity 12 months prior and 36 months following VNS implantation were compared. Per-quarter average resource use was evaluated in order to provide a normalised measure of resource use for comparison across unequal windows of observation (see Fig. 1).

Patients were identified for inclusion in the sample using a combination of diagnosis and intervention codes. To determine that the patient had undergone VNS implantation to treat epilepsy, they had to have an in-patient or out-patient record between April 2006 and July 2014 containing diagnosis codes G40 'Epilepsy' and/or G41 'Status epilepticus'. April 2006 was the earliest point from which patient data was available, and so data from this point was included in the identification window to ensure the largest pool of epilepsy patients possible.

In addition they also had to have an in-patient or out-patient record between April 2009 and July 2011 containing procedure code A33.1 'Introduction of neurostimulator into cranial nerve' and the site of intervention code Z04.4 'Vagus nerve (x)'. Transcutaneous stimulator (OPCS code Y90.1) was not included in the study sample.

Patients with a VNS implantation date between 1st April 2009 and 31st July 2011 were selected in order to ensure that all patients had at least the required observation period for comparison (one year prior and three years post VNS implantation). Reliable A&E data is available from 1st April 2008 so an inclusion date of 1st April 2009 was required in order to allow all patients at least four quarters of reliable A&E attendance data.

Patient resource utilisation was calculated retrospectively and normalised to average (mean) visits/days per quarter. This allows fair comparison of the pre-VNS of 12 months and post-VNS period of 36 months, taking into account the unequal window of observation in the two periods. Resource use before and after VNS was identified outside of the episode of implantation, so resource use attributed to either the 'before' or 'after' intervention period did not include the in-patient episode in which the patient received the implant. To match the American study [13], each patient's observation period extended from the index date until removal of the device, death or end of the study period (maximum 3 years of follow-up), whichever occurred first.

3. Data analysis

Descriptive statistics were used to summarise patient demographics, patient pathways, and VNS usage and to assess resource use comparing the before and after VNS periods. Means and proportions were reported on continuous variables, proportion and frequency on categorical variables. Trends of activity over time were determined comparing the average quarterly resource use before VNS and quarterly resource use data following VNS. This trend data was subsequently tested using the Wilcoxon

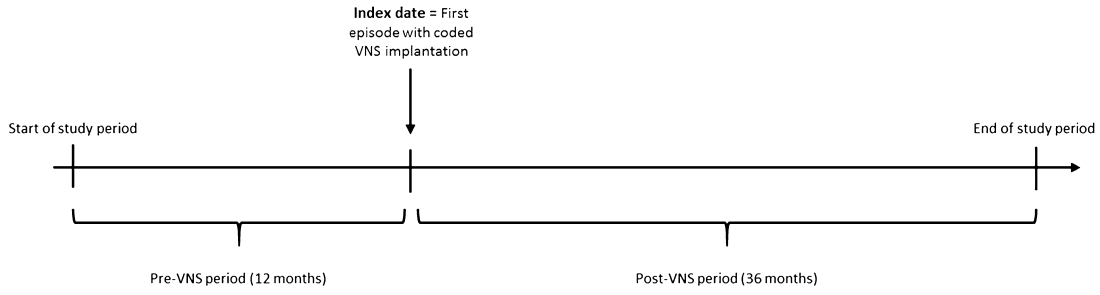

Fig. 1. Study design.