A preliminary cost-utility analysis of non-invasive vagus nerve stimulation therapy in patients suffering with headache and functional disorder multi-morbidity

Michelle Jenks[1], Steve Davis[2], Frank Amato[3], J.P. Errico[3], Iain Strickland[3]

1 York Health Economics Consortium, Enterprise House, Innovation Way, University of York, Heslington, York, YO10 5NQ

2 Interface Clinical Services, Leeds, United Kingdom

3 electroCore LLC, Basking Ridge, NJ, USA

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BACKGROUND AND OBJECTIVES

Non-invasive vagus nerve stimulation (nVNS), delivered via the therapeutic medical device gammaCore® (electroCore LLC, New Jersey, United States of America), has been shown to be efficacious in the treatment of primary headache disorders [1]. Previous analyses have demonstrated that nVNS delivered by gammaCore (gC) is a cost-effective treatment in patients with cluster headaches [2].

nVNS improves the quality of life for patients suffering with multiple, medically unexplained, functional disorders such as headache, gastric mobility disorders, depression and anxiety [3]. Multi-morbidity typically describes individuals with two or more chronic medical conditions. These individuals may experience reduced quality of life, functional decline and increased use of healthcare resources [4]. Within the United Kingdom (UK), it is estimated that one in six patients are multi-morbid and that around one third of all general practice consultations are for multi-morbid patients [4].

The objective of this study was to estimate the cost-utility of nVNS therapy plus standard care in patients suffering with headache and functional disorder multi-morbidity versus standard care alone. The analysis was conducted from a UK National Health Service (NHS) perspective.

Table 1: Key model input parameters

Resource usage input parameters (per person per month)	nVNS + standard care	Standard care	Source
GP consultations	0.43	0.54	NHS cohort study [4]
Prescriptions	3.81	3.65	NHS cohort study
Secondary care visit	0.08	0.10	NHS cohort study

Unit costs	Input parameter	Source
GP consultation	£38	PSSRU [5]
Secondary care	£111	NHS reference cost [6]
Prescription cost	£8.25	NHS cohort study
nVNS cost	£400 per 8 weeks with free initial period	electroCore

METHODS

A decision analytic model was developed in Microsoft Excel to estimate the cost-utility of nVNS over both a one-year and two-year time horizon. The model utilised EQ-5D-5L and healthcare resource data collected from a cohort study set in nVNS primary care clinics within the NHS designed to treat multi-morbid patients (n=233) [3]. Included patients had two or more diagnoses codes under the following disorders: headache, anxiety or depression, gastrointestinal disorders, pain, sinobronchial symptoms, tinnitus or epilepsy. Resource use data were combined with unit cost data to determine the cost implications of multi-morbid patients either with or without the use of nVNS. Costs included within the model comprised primary care visits; prescription costs; secondary care visits and device related costs. Device costs were applied for the duration during which patients remained on treatment. Participants were instructed to use the device bilaterally, three times a day. Utility scores were elicited using the EQ-5D-5L scores collected at baseline and every four weeks during the clinical study and applying Kaplan-Meier methods to account for censoring. Utility at baseline was used in the standard care arm of the model. The key input parameters are shown in Table 1.

The primary outcome of the model was an estimated incremental cost per quality adjusted life year (QALY) comparing nVNS + standard care, to standard care alone over a 12 month period. Deterministic sensitivity analyses (DSA) were conducted to assess the impact of bias on the results of the model. Exploratory analysis were also conducted by extrapolating the data over a two-year time horizon.

RESULTS

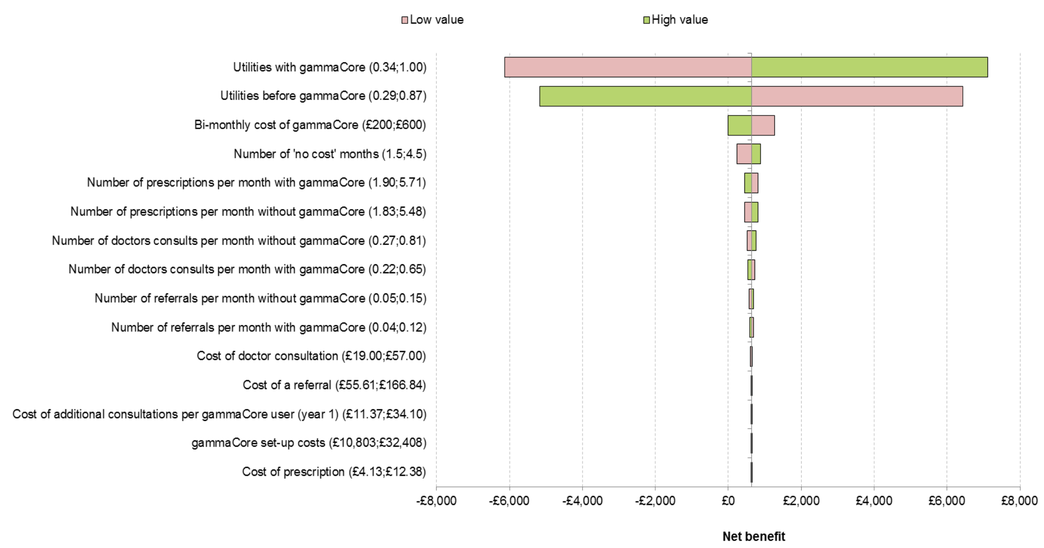
Over a one-year time horizon comparing nVNS + standard care with standard care alone, an ICER of £13,368 per QALY is estimated (Table 2). nVNS would, therefore, be considered cost-effective at a £20,000 per QALY threshold. Cost savings are generated from a reduction in GP consultation costs and a reduction in referrals to secondary care, whilst device related and additional prescription costs are incurred. A 0.1 QALY gain per patient is estimated. Based upon a £20,000 per QALY threshold, a net monetary benefit of £631 per patient and net health benefit of 0.03 per patient are derived.

DSA demonstrated the utility values in both arms of the model to be key drivers of the analysis (Figure 1). nVNS remains cost-effective at a £20,000 per QALY threshold where the difference in QALYs per patient is 0.065 or greater. An exploratory analysis conducted over a 2-year time horizon estimated ICERs of between £11,194 and £15,067 per QALY depending upon the extrapolation method used.

Table 2: Estimated results at one-year

	nVNS + standard care	Standard care	Incremental
Costs per person	£2,015	£743	£1,272
QALYs per person	0.68	0.58	0.10
ICER		£13,368	

Figure 1: Tornado diagram



CONCLUSIONS

Based on preliminary data, from a UK NHS perspective, nVNS + standard care is estimated to be cost-effective at a £20,000 per QALY threshold compared to standard care alone in patients with functional multi-morbidities. The use of comparative clinical data within the model would strengthen these conclusions.

REFERENCES

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CONTACT US

michelle.jenks@york.ac.uk
Telephone: +44 1904 324870
Website: www.yhec.co.uk
http://www.minerva-network.com/
http://tinyurl.com/yhec-facebook
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