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Original article

InnovaSEC in Action: Cost-effectiveness of Barostim in the Treatment of Refractory Hypertension in Spain

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ABSTRACT

Introduction and objectives: In Spain, 0.3% of patients with hypertension are refractory to conventional treatment. The complications resulting from deficient control of this condition can lead to poor quality of life for the patient and considerable health care costs. Barostim is an implantable device designed to lower blood pressure in these patients. The aim of this study was to analyze the cost-effectiveness of Barostim compared with drug therapy in hypertensive patients refractory to conventional treatment (at least 3 antihypertensive drugs, including 1 diuretic agent).

Methods: We used a Markov model adapted to the epidemiology of the Spanish population to simulate the natural history of a cohort of patients with refractory hypertension over their lifetime. Data on the effectiveness of the treatments studied were obtained from the literature, and data on costs were taken from hospital administrative databases and official sources. Deterministic and probabilistic sensitivity analyses were conducted.

Results: Barostim increased the number of quality-adjusted life years by 0.78 and reduced the number of hypertension-associated clinical events. The incremental cost-effectiveness ratio in a cohort of men reached 68 726 euros per year of quality-adjusted life. One of the main elements that makes this technology costly is the need for battery replacement. The results were robust.

Conclusions: Barostim is not a cost-effective strategy for the treatment of refractory hypertension in Spain. The cost-effectiveness ratio could be improved by future reductions in the cost of the battery.

InnovaSEC en acción: coste-efectividad de Barostim para el tratamiento de la hipertensión arterial refractaria en España

Palabras clave:
Coste-efectividad
Hipertensión refractaria
Infarto de miocardio
Accidente cerebrovascular

RESUMEN

Introducción y objetivos: En España, el 0,3% de los pacientes hipertensos son refractarios al tratamiento convencional. Las complicaciones derivadas de un control deficiente se traducen en mala calidad de vida para el paciente y un coste importante para el sistema sanitario. Barostim es un dispositivo implantable que busca reducir la presión arterial de estos pacientes. El objetivo del presente estudio es analizar el coste-efectividad de Barostim comparado con terapia farmacológica en pacientes hipertensos refractarios al tratamiento convencional (al menos tres fármacos antihipertensivos, siendo uno de ellos un diurético).

Métodos: Modelo de Markov adaptado a la epidemiología de la población española que simula la historia natural de una cohorte de pacientes con hipertensión arterial refractaria a lo largo de su vida. Los datos sobre efectividad de los tratamientos se obtuvieron de la literatura y los de costes, de bases de datos administrativas hospitalarias y de fuentes oficiales. Se realizaron análisis de sensibilidad determinístico y probabilístico.

Resultados: Barostim redujo los eventos clínicos asociados a la hipertensión y aumentó en 0,78 el número de años de vida ajustados por calidad. El cociente de coste-efectividad incremental para una cohorte de varones alcanzó los 68.726 euros por año de vida ajustado por calidad. Uno de los principales elementos que encarece la tecnología es el coste del recambio de la batería. Los resultados fueron robustos.

Conclusiones: Barostim no es una estrategia coste-efectiva para el tratamiento de la hipertensión refractaria en España. Reducciones futuras en el precio de la batería mejorarían su cociente de coste-efectividad.

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Abbreviations

AMI: acute myocardial infarction
CVA: cerebrovascular accident
ICER: incremental cost-effectiveness ratio
QALY: quality-adjusted life year
SBP: systolic blood pressure

INTRODUCTION

Within the health sector, innovation is the key to progress in scientific research, patient care, and business-related concerns. Nonetheless, the introduction of new medical technology should provide substantial added value in regular clinical practice. For this reason, the Spanish Society of Cardiology (*Sociedad Española de Cardiología* [SEC]) has implemented the strategic initiative, InnovaSEC, to analyze the value of new technology contemplated for use in the Spanish health care setting.[1] The first new product evaluated under the auspices of InnovaSEC is the Barostim medical device.

Barostim (CVRx Inc., Minneapolis, Minnesota, United States) is an implantable system that lowers blood pressure by electrical stimulation of the carotid baroreceptors. It is indicated as a second-line treatment for hypertensive patients resistant to conventional medical therapy (established on systolic blood pressure [SBP] values $\geq$ 140 mmHg, despite the use of at least 3 antihypertensive drugs, including a diuretic). Refractory hypertension affects 0.3% of hypertensive Spanish patients.[2] Considering that the prevalence of hypertension in the Spanish population older than 30 years is around 30%,[3] there would be approximately 29 000 patients with hypertension refractory to drug therapy in Spain.

Carotid baroreceptor stimulation is considered a possible therapeutic option for refractory hypertension in the guidelines of the European Society of Hypertension and the European Society of Cardiology.[4] Furthermore, the indication for Barostim in patients refractory to conventional treatment was found to be cost-effective for the German population (cost-effectiveness ratio, 7797 euros/quality-adjusted life year [QALY]).[5] However, the epidemiologic profile of the Spanish population and the cost of treating hypertension and its complications in Spain differ from those observed in northern European countries, and both these variables could have a considerable impact on the cost-effectiveness of this technology in our country.

The aim of this study was to analyze the cost-effectiveness of Barostim as a second-line treatment compared with an adequate pharmacologic regimen (at least 3 antihypertensive drugs, including a diuretic agent) in the population of adults with hypertension (SBP $\geq$ 140 mmHg), from the perspective of the publically-funded Spanish Health System.

METHODS

Design

A cost-effectiveness analysis was conducted using a model developed by Markov[6] in which patients start in hypertensive status refractory to drug therapy and progress over time toward several possible health states (Figure 1). Time is represented as fixed cycles of 1 month's duration up to the end of the patients' lives. The probability of transition to a new state depends on the patients' initial characteristics and later ones, their health status, and the treatment received. Different quality of life levels and costs are associated with each health state. The model was based on a study carried out in the German population,[5] and was adapted to the epidemiologic characteristics and health costs of Spain for the present study.

The following health states were included in the model: high blood pressure, ischemic heart disease, heart failure, acute

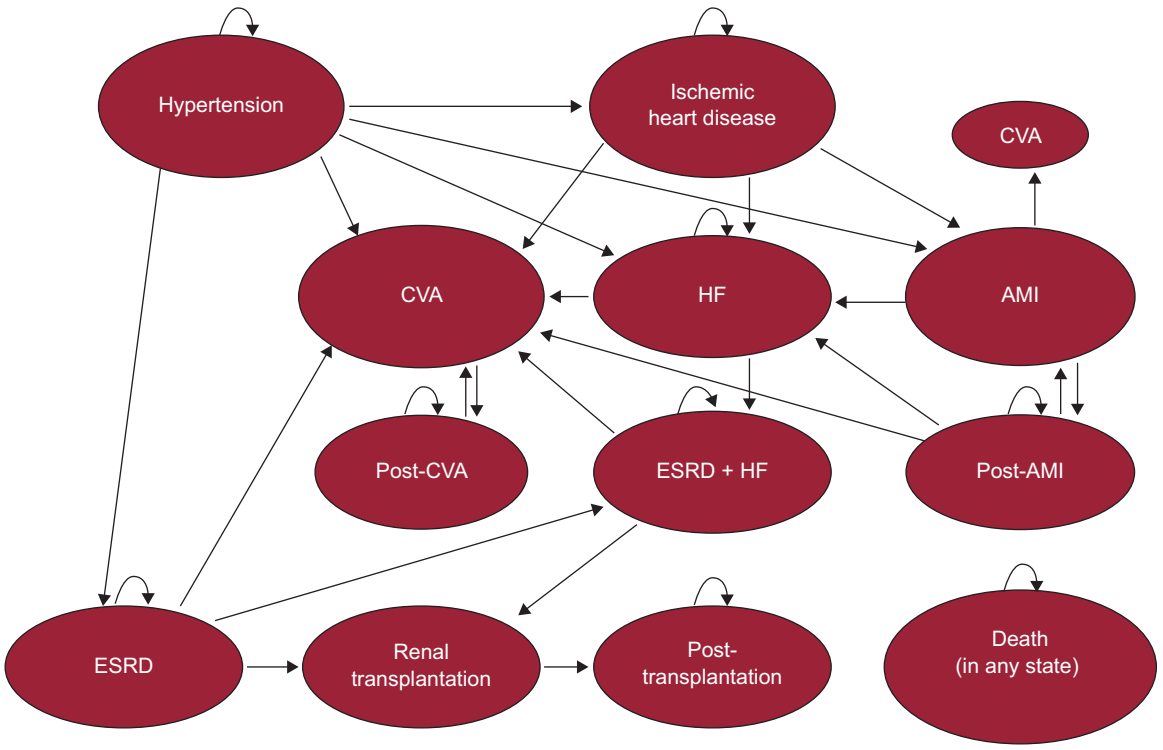

Figure 1. Markov model for hypertensive patients refractory to pharmacological treatment. AMI, acute myocardial infarction; CVA, cerebrovascular accident; ESRD, end-stage renal disease; HF, heart failure.