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Value-based procurement of medical devices: Application to devices for mechanical thrombectomy in ischemic stroke

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ABSTRACT

Objectives: In the acute ischemic stroke, endovascular devices have shown promising clinical results and are also likely to represent value for money, as several modeling studies have shown. Pharmacoeconomic evaluations in this field, however, have little impact on the procurement of these devices. The present study explored how complex pharmacoeconomic models that evaluate effectiveness and cost can be incorporated into the in-hospital procurement of thrombectomy devices.

Patients and methods: As regards clinical modeling, we extracted outcomes at three months from randomized trials conducted for four thrombectomy devices, and we projected long-term results using standard Markov modeling. In estimating QALYs, the same model was run for the four devices. As regards economic modeling, we firstly estimated for each device the net monetary benefit (NMB) per patient (threshold = $60,000 per QALY); then, we simulated a competitive tender across the four products by determining the tender-based score (on a 0-to-100 scale). Prices of individual devices were obtained from manufacturers. Extensive sensitivity testing was applied to our analyses.

Results: For the four devices (Solitaire, Trevo, Penumbra, Solumbra), QALYs were 1.86, 1.52, 1,79, 1.35, NMB was $101,824, $83,546, $101,923, $69,440, and tender-based scores were 99.70, 43.43, 100, 0, respectively. Sensitivity analysis confirmed findings from base-case.

Conclusion: Our results indicate that, in the field of thrombectomy devices, incorporating the typical tools of cost-effectiveness into the processes of tenders and procurement is feasible. Bridging the methodology of cost-effectiveness with the every-day practice of in-hospital procurement can contribute to maximizing the health returns that are generated by in-hospital expenditures for medical devices.

1. Introduction

The regulation of medical devices in Europe is less rigorous than that in the United States [1–3] particularly because there is no European Agency for medical devices and also the national management of devices is scarce, especially regarding terms of cost-effectiveness analysis. While the cost-effectiveness evaluation of these products in Europe is mainly carried out by academic institutions, this academic activity has little or no impact on the administrative procurement in national health systems. Also, procurement processes show marked differences between countries, but differences within country exist.

When the procurement involves a class of medical devices rather than a specific device made by a single manufacturer, some countries run competitive tenders aimed at the procurement of devices that possess similar characteristics; however, an overall rationale regarding cost-effectiveness is lacking, even in the countries where these tenders are frequently carried out.

After completing a pilot experience in which we applied an original value-based method to the procurement of hip replacement prostheses [4], we tried the application of the same method to the class of devices employed for endovascular thrombectomy after acute ischemic stroke. This class was selected because it met each of the following characteristics: a) presence of a common clinical indication; b) presence of more than one device in the market [5,6]; c) similar costs of implantation among the different devices [5]; d) availability of simulation models evaluating the clinical benefit yielded on the long-term [7–14].

The aim of our study was to evaluate the cost-effectiveness profile (expressed as net monetary benefit, NMB) of devices for mechanical thrombectomy in combination with intravenous t-PA compared with intravenous t-PA alone in acute ischemic stroke and to calculate, based on the results of cost-effectiveness analysis, a score for each device to be used in the procurement process.

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2. Patients and methods

2.1. Study design

We firstly selected the devices possessing all the characteristics needed for our project, and we retrieved from the published literature the simulation models suitable for estimating both short-term and long-term clinical benefits. Finally, we incorporated into this model the measures of clinical outcome reported in the clinical studies focused on each device and we estimated quality-adjusted life years (QALYs) per patient and the net monetary benefit (NMB [4,15,16]) per patient expected for each device. Current list prices for the devices were employed in the latter analysis. We also tested the relationship between the NMB and the cost of the device by simulating a tender comparing the four different devices with one another. The mathematical algorithm for performing this simulated tender was based on the assumption of maximizing the NMB.

2.2. Selection of devices and current list prices

A search of the medical literature (search engine = Pubmed; search terms: “thrombectomy AND stroke”; date of the last search: 24 October 2017) identified several devices with which thrombectomy has been carried out in the past years. Among these, we kept in our analysis only those devices that proved to be still in use in European countries or the US. This point was addressed by consulting devices’ manufacturers. In our analysis, we used the price reported by the respective manufacturer for each device [5].

2.3. Simulation models developed for evaluating devices for endovascular thrombectomy

Another search of the medical literature (search engine = Pubmed; search term: “markov AND thrombectomy AND stroke”; date of last search: 31 October 2017) was conducted for the selection of the most suitable simulation model for our analysis.

2.4. Clinical measures employed for feeding the model

The following outcomes were considered after the first stroke: a) mRS of 0–2; b) mRS of 3–5; c) death; the same three outcomes could also occur after a recurrent stroke. People whose outcome was mRS 3–5 after the first stroke could have the following two outcomes after a recurrent stroke: a) mRS of 3–5; or b) death; in contrast, people whose outcome was mRS 0–2 after the first stroke could have the following three outcomes after a recurrent stroke: a) mRS of 0–2; b) mRS of 3 to 5; c) death.

2.5. Utilities

The utility was assumed to be 0.74 for mRS 0–2 and 0.38 for mRS 3–5 according to published information [12].

2.6. Life expectancy in the Markov model

The life-expectancy attributed to the simulated patients was determined by considering: a) the age-related and gender-related mortality of a normal population [20]; b) the mortality attributable to stroke. These two factors [i.e. (a) and (b)] were separately managed in two different sections of the Markov model.

2.7. Estimation of QALYs

For the endovascular device, QALYs were computed by the health states of the model and their corresponding transition probabilities.

2.8. Calculation of net monetary benefit

Two approaches are most frequently employed to estimate the cost-effectiveness of an innovative treatment in comparison with the previous standard of care. The first approach relies on the calculation of the incremental cost-effectiveness ratio (ICER); then, the ICERs of individual treatments are compared with the pre-determined cost-effectiveness threshold so that treatments with a better ICER than the threshold are assigned a favourable pharmacoeconomic profile whereas treatments with a worse ICER than the threshold are assigned an unfavourable pharmacoeconomic profile; furthermore, individual treatments are ranked in their cost-effectiveness according to their respective ICERs.

While this first approach is based on computing the ratio from the above parameters, the second approach (commonly referred to as NMB [4,15,16]) is based on a calculation wherein the main parameters are summed up with one another. The main equation of this second approach is the following:

NMB = [clinical benefit of device converted into a monetary equivalent] − [cost of device] − [other treatment-related costs]

where:

- the clinical benefit of the device (expressed in QALYs) is converted into a monetary benefit (expressed in $) by using a pre-determined cost-effectiveness threshold (e.g., $60,000 per QALY gained).
- the cost of the device is expressed in $.
- the other costs (OCs) are represented by a series of items that should be qualitatively the same across all treatments under examination. These OCs never include the cost of the device, but always include the costs, other than the device cost, incurred on the short term (e.g., accessories such as separator wires, canisters, suction tubings, balloon guides etc.). Also, depending on the specific disease condition under examination and the type of information available, these OCs may also include the costs incurred by the patients in the long term. This latter approach allows us to account for the long-term economic consequences of managing patients with a favorable clinical outcome as opposed to patients with a less favorable clinical outcome. For example, long-term costs are known to differ between patients achieving a mRS of 0–2 after the stroke and those achieving a mRS of 3–5 after the stroke [13]. Finally, the perspective of the pharmacoeconomic analyses described in this paper was that of a national health system; direct costs were included, whereas indirect costs were left out.

2.9. Tender simulation

We employed the values of NMB (separately calculated for the individual devices) to generate a ranking across the comparators. This ranking was initially expressed in monetary units and then converted into a 0-to-100 scale where 0 is the score assigned to the worst comparator, and 100 is the score assigned to the best comparator. Comparators associated to an intermediate ranking on the NMB scale were converted into an intermediate score on 0-to-100 scale (i.e., a score greater than 0 and lower than 100 and based on a nonlinear proportionality). For administrative reasons, this score on 0-to-100 scale is mandatory in European tenders [21,22]; its equation is as follows:

$$\text{score} \frac{\text{NMB}_{\text{device under examination}} - \text{NMB}_{\text{device with the worst score}}}{\text{MB}_{\text{device with the best score}} - \text{NMB}_{\text{device with the worst score}}} \times 100$$

The above equation is available for online use at http://www.osservatorioinnovazione.net/tenders/nmb.php