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 0-100 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.

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:

\[
\text{NMB} = \left[\text{clinical benefit of device converted into a monetary equivalent}\right] - \left[\text{cost of device}\right] - \left[\text{other treatment-related costs}\right]
\]

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 0-100 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 0-100 scale (i.e., a score greater than 0 and lower than 100 and based on a nonlinear proportionality). For administrative reasons, this score on 0-100 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

2.10. Base-case analysis

In our base-case analysis, the Markov model was implemented according to a time horizon of 5 years. The yearly discount rate was 3.5% in keeping with Ganeshalingam et al. [12]. This rate was applied to both costs and benefits. The length of one cycle was one year. The device cost was handled as the cost of the kit including all devices needed for the intervention. The yearly long-term cost of patient management was kept at 0 for all devices under comparison (but this item was instead accounted for in a sensitivity analysis; see below).

2.11. Sensitivity analysis

A series of sensitivity analyses were performed in which the following items were varied as indicated below:

- willingness-to-pay threshold of $30,000 or $120,000;
- time horizon of 10 and 20 years;
- yearly discount of 0% and 1.5%.
- the long-term cost of patient management: these values were set at $771.88 every three months for patients with mRS 0–2 and $2074.62 every three months for patients with mRS 3–5; 12 hence, the yearly costs for our model were $3087.52 and $8298.48, respectively.
- These variations were tested one at a time, and their effects on QALYs and simulated tenders (see below) were estimated.

3. Results

3.1. Thrombectomy devices identified through the literature search

Our search of the medical literature identified five devices employed in thrombectomy interventions (namely, Solitaire, Trevo, Merci, Penumbra, Solumbra). Four of these (Solitaire, Trevo, Penumbra, Solumbra) proved to be currently in use.

3.2. Selection of a single model and adaptation to the Treeage software

The search of the medical literature identified a large series of models developed for evaluating these devices [7–14]. In the comparison of the above Markovian models with one another, a consensus was reached among the authors of the present paper that the model described by Ganesalingam et al. [12] was the one most suitable for our analysis. Hence, this model was adapted to the language of the Treeage software (TreeAge Pro 2011). Furthermore, the management of recurrent stroke was adapted to the design published by Leppert et al. [9]. The final version of this re-adapted Markov model has been published elsewhere [23]. The probabilities of individual transitions based on mRS scores for each device at three months are reported in Table 1 with the corresponding references. Further details on the model are reported in Appendix A.

3.3. Base-case analysis

Table 2 shows the values of QALYs and NMB estimated in our base-case analysis (in which a time horizon of 5 years, a yearly discount rate of 3.5% and a willingness-to-pay threshold of $60,000 were used). The device cost was the cost of the kit of all devices needed for the endovascular procedure (see Miskolcz [5]). Since OCs were considered to be the same across all devices under examination, they were not included in the calculation of NMB. Of course, the methodological approach will remain the same if costs are expressed according to another currency (such as euros).

3.4. Sensitivity analysis

The results are summarized in Table 3.

4. Discussion

From a methodological viewpoint, modeling the clinical outcomes after acute ischemic stroke is the core of all research focused on the cost-effectiveness of these devices. At present, at least in the field of implantable medical devices, this type of research has mainly a speculative value and, in practice, is not applied in the procedures for device acquisition. More precisely, the results of cost-effectiveness studies on medical devices are reported quite frequently in scientific journals, but in real life the procurement process continues to be based on the “traditional” work of administrative offices, where outcomes are managed through qualitative indexes or, at best, through scores and algorithms developed at local level. According to these scores, clinical results and comparative effectiveness do not play any direct role in decision making; in fact, most of the scores and ranking algorithms employed in ‘traditional’ tenders do not differentiate between medical devices and materials not designed to yield a clinical benefit.

The situation is completely different in the field of drugs. In fact, in many countries cost-effectiveness research on pharmacological treatments has an extensive application in the everyday practice of price setting, inasmuch as the national health systems of these countries employ the rules of cost-effectiveness to establish the prices at which medicines are reimbursed.

The experience described in this paper has a two-fold value. Firstly, while most of the methodology of the present paper is similar to that employed in numerous recent cost-effectiveness studies, the originality of the present work lies in our attempt to directly link the clinical out-

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### Table 1

<table>
<thead>
<tr>
<th>Device name</th>
<th>Outcome at 3 months</th>
<th>Number of patients</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mRS 0-2</td>
<td>mRS 3-5</td>
<td>mRS 6</td>
</tr>
<tr>
<td>Solitaire FR</td>
<td>0.54</td>
<td>0.34</td>
<td>0.12</td>
</tr>
<tr>
<td>Trevo Retrievers&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.30</td>
<td>0.55</td>
<td>0.15</td>
</tr>
<tr>
<td>Penumbra SMAX ACE with ADAPT technique</td>
<td>0.55</td>
<td>0.27</td>
<td>0.18</td>
</tr>
<tr>
<td>Solumbra</td>
<td>0.31</td>
<td>0.40</td>
<td>0.29</td>
</tr>
</tbody>
</table>

<sup>a</sup> Percent transition probabilities are expressed on a 0-to-1 scale.

<sup>b</sup> The patients of this cohort are a sub-group of those evaluated in the study of Beckhemer et al. [18].

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comes with the administrative decisions (namely, the decisions adopted for the procurement of devices). With regard to other implantable devices aimed at other disease conditions (e.g. bioresorbable coronary stents, mitral valve repair, and atrial appendage closure devices), we have recently completed other studies similar to the present one, in which this approach has shown a good performance as well (Messori et al., unpublished data) [4,25,26]. Secondly, the use of different simulation models in this disease condition is likely to introduce an important bias that increases the heterogeneity of cost-effectiveness results. Hence, the solution that we propose herein is to study the different devices with exactly the same model, but to feed the model with different, device-specific parameters; this solution seems to be preferable than using different models for different devices.

The results of our base-case analysis confirmed the clinical evidence arising from the clinical trials. In this respect, the ranking in effectiveness from our study was headed –as expected- by Solitaire and Penumbra (the QALYs of which were nearly identical), followed by the other two devices. Likewise, Solitaire and Penumbra showed the best values of NMB thus indicating that these two devices have a more favorable cost-effectiveness profile in comparison with the others. The same result was given also by the tender scores that were nearly identical for Solitaire and Penumbra. Finally, it should be noted that the approach based on NMB conveyed the same cost-effectiveness message that would be obtained using the classic comparative analysis based on ICERs (data not shown). Interestingly enough, our analysis on simulated tenders indicated, though at a preliminary level, that the NMB had a good performance in capturing the differences in effectiveness among different devices and, more importantly, the method succeeded in assigning a “fair” economic value to the increased effectiveness demonstrated by the two most effective devices.

When this information about ranking in effectiveness was converted from NMB into the tender score, the scores (as expected) confirmed the various rankings in qualitatively terms and, quite importantly, also demonstrated a sufficient performance in quantitative terms. Hence, although NMB worked on a direct-proportionality linear scale whereas the tender scores followed a nonlinear relationship with NMB, their respective results reflected the same message concerning comparative effectiveness and cost-effectiveness ranking.

The results of our base-case analysis were expressed by calculating the various parameters one at a time for each of the four devices; this required a quite extensive presentation of the results reported for each analysis (given that each analysis generated, for each device, the values of QALYs, NMB, and tender score). In consideration of the large amount of data generated by each analysis, the series of sensitivity analyses planned in our study was kept to a minimum; in particular, we changed each of the various parameters one at a time without eval-

| Table 2 | Base-case analysis: QALYs, NMB, and tender score for each device. |
|---------|---------------------|---------------------|---------------------|
|         | Solitaire FR | Trevo Retriever | Penumbra SMAX ACE with ADAPT technique | Solumbra |
| QALYs   | 1.86        | 1.52           | 1.79                | 1.35       |
| Device cost* | 9776*       | 7654*          | 5477*               | 11,560*    |
| OCEs per patient** | –          | –              | –                   | –          |
| NMB per patient*** | 101,824    | 83,546         | 101,923             | 69,440     |
| Tender score | 99.70     | 43.43          | 100                 | 0          |

**Table 3**

<table>
<thead>
<tr>
<th>Willingness-to-pay threshold of $30,000 QALYs</th>
<th>Solitaire FR</th>
<th>Trevo Retriever</th>
<th>Penumbra SMAX ACE with ADAPT technique</th>
<th>Solumbra</th>
</tr>
</thead>
<tbody>
<tr>
<td>QALYs</td>
<td>1.86</td>
<td>1.52</td>
<td>1.79</td>
<td>1.35</td>
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<tr>
<td>NMB per patient (§)</td>
<td>46,024</td>
<td>37,946</td>
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<td>28,940</td>
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<td>Tender score (§)</td>
<td>88.60</td>
<td>46.70</td>
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<table>
<thead>
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<th>Willingness-to-pay threshold of $120,000 QALYs</th>
<th>Solitaire FR</th>
<th>Trevo Retriever</th>
<th>Penumbra SMAX ACE with ADAPT technique</th>
<th>Solumbra</th>
</tr>
</thead>
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<tr>
<td>QALYs</td>
<td>1.86</td>
<td>1.52</td>
<td>1.79</td>
<td>1.35</td>
</tr>
<tr>
<td>NMB per patient (§)</td>
<td>213,424</td>
<td>174,746</td>
<td>209,323</td>
<td>150,440</td>
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<td>Tender score (§)</td>
<td>100</td>
<td>38.59</td>
<td>93.49</td>
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<th>Time horizon of 10 years</th>
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<th>Trevo Retriever</th>
<th>Penumbra SMAX ACE with ADAPT technique</th>
<th>Solumbra</th>
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<tr>
<td>QALYs</td>
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<td>2.96</td>
<td>3.46</td>
<td>2.87</td>
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<tr>
<td>NMB per patient (§)</td>
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<td>169,947</td>
<td>202,124</td>
<td>160,641</td>
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<td>Tender score (§)</td>
<td>100</td>
<td>20.69</td>
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<th>Time horizon of 20 years</th>
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<th>Penumbra SMAX ACE with ADAPT technique</th>
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<td>QALYs</td>
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<tr>
<td>NMB per patient (§)</td>
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<td>164,547</td>
<td>317,324</td>
<td>257,841</td>
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<tr>
<td>Tender score (§)</td>
<td>100</td>
<td>0</td>
<td>94.49</td>
<td>57.70</td>
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<table>
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<tr>
<th>Yearly discount rate of 0%</th>
<th>Solitaire FR</th>
<th>Trevo Retriever</th>
<th>Penumbra SMAX ACE with ADAPT technique</th>
<th>Solumbra</th>
</tr>
</thead>
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<tr>
<td>QALYs</td>
<td>2.30</td>
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<td>1.96</td>
<td>1.61</td>
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<tr>
<td>NMB per patient (§)</td>
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<td>91,947</td>
<td>112,124</td>
<td>85,041</td>
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<td>Tender score (§)</td>
<td>100</td>
<td>15.99</td>
<td>62.71</td>
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<th>Yearly discount rate of 1.5% QALYs</th>
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<tbody>
<tr>
<td>QALYs</td>
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<td>1.60</td>
<td>1.88</td>
<td>1.55</td>
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<tr>
<td>NMB per patient (§)</td>
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<td>Tender score (§)</td>
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<th>Inclusion of long-term cost</th>
<th>Solitaire FR</th>
<th>Trevo Retriever</th>
<th>Penumbra SMAX ACE with ADAPT technique</th>
<th>Solumbra</th>
</tr>
</thead>
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<td>QALYs</td>
<td>1.86</td>
<td>1.52</td>
<td>1.79</td>
<td>1.35</td>
</tr>
<tr>
<td>Long-term cost per patient (§)</td>
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<td>18,513</td>
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<tr>
<td>NMB per patient (§)</td>
<td>101,809</td>
<td>65,033</td>
<td>88,472</td>
<td>54,981</td>
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<tr>
<td>Tender score (§)</td>
<td>100</td>
<td>21.46</td>
<td>71.52</td>
<td>0</td>
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</table>

The device cost was $7976, $7654, $5477 and $11,560 for Solitaire FR, Trevo Retriever, Penumbra SMAX ACE with ADAPT Technique, and Solumbra, respectively. OCs are not reported since they were considered to be the same across all devices.

* The yearly long-term cost was $3087.52 for patients with mRS of 0-2 and $8298.48 for patients with mRS of 3-5 according to Ganesalingam et al. [12].

The results of our base-case analysis, considered together with the results of the sensitivity analyses, are reported in Table 3. The results of the sensitivity analyses are always in line with our expectations based on clinical findings (i.e. QALYs) or on pharmacoeconomic indexes (i.e. NMB and tender scores).
The findings from our sensitivity testing underscored also the robustness of the our base-case analysis. On the other hand, one limitation of our approach is that the effectiveness of Solitaire was supported by a larger population of patients than that of Penumbra, but the evaluation of effectiveness in our base-case analysis did not account for this factor; in this context, a further sensitivity analysis focused on the statistical variability of estimated values of QALYs could have been worthwhile.

5. Conclusions

Our results indicate that, in the field of medical devices, these attempts to incorporate the typical tools of cost-effectiveness into the processes of tendering and procurement [4] are promising. Bridging the methodology of cost-effectiveness with the everyday practice of procurement can contribute to maximize the health returns that are generated, particularly by the in-hospital expenditures for medical devices. This methodological approach can therefore promote the application to medical devices of the same value-based principles that are currently applied to the most relevant pharmaceuticals [27,28].

Conflict of interest

The authors declare that they have no conflicts of interest.

Acknowledgement

There were no external sources for funding the present study

Appendix A. Markov model

The basic characteristics of the present model have been published elsewhere [24].

States of the Markov model and transition probabilities

The starting point of the simulation model is a Markov node (circular M) from which branches originate. The first is a transitory health state, the second is functional independence after first stroke, the third is functional dependence after first stroke, the fourth is death. The symbols adopted in this scheme reflect the syntax required by the Treenique software.

Variables included in the model (Solitaire): death2str = 0.19 (death rate after recurrent stroke according to Leppert et al. [9]); disc_rate = 0.035 (annual discount rate); inc2stroke = 0.05 (annual incidence of recurrent stroke according to Leppert et al. [9]); mRS0–2 = 0.32 (percentage of patients achieving functional independence after first stroke according to HOO [17]); mRS3–5 = 0.33 (the same for functional dependence); mRS6 = 0.19 (death rate after first stroke according to HOO [17]); ut2stroke = 0.34 (utility after recurrent stroke according to Ganesalingham et al. [12]); ut_mild = 0.74 (utility after mild stroke according to Ganesalingham et al. [12]); ut_mose = 0.38 (utility after moderate/severe stroke according to Ganesalingham et al. [11]); STAGE = 20 (time horizon in years). The two probabilities, whose value is 0.405, are not supported by any specific reference, but reflect expert opinion.

Variables included in the model (Trevo): death2str = 0.19 (death rate after recurrent stroke according to Leppert et al. [9]); dis_c_rate = 0.035 (annual discount rate); inc2stroke = 0.05 (annual incidence of recurrent stroke according to Leppert et al. [9]); mRS0–2 = 0.33 (percentage of patients achieving functional independence after first stroke according to Berkhemer et al. [18]); mRS3–5 = 0.46 (the same for functional independence); mRS6 = 0.21 (death rate after first stroke according to Leppert et al. [9]); ut2stroke = 0.34 (utility after recurrent stroke according to Ganesalingham et al. [12]); ut_mild = 0.74 (utility after mild stroke according to Ganesalingham et al. [12]); ut_mose = 0.38 (utility after moderate/severe stroke according to Ganesalingham et al. [11]); STAGE = 20 (time horizon in years). The two probabilities, whose value is 0.405, are not supported by any specific reference, but reflect expert opinion.

Abbreviations: RWD, reward (which in this model represents the incremental increase in quality-adjusted survival).

Variables included in the model (Penumbra and Solumbra): death2str = 0.19 (death rate after recurrent stroke according to Leppert et al. [9]); disc_rate = 0.035 (annual discount rate); inc2stroke = 0.05 (annual incidence of recurrent stroke according to Leppert et al. [9]); mRS0–2 = 0.33 (percentage of patients achieving functional independence after first stroke according to Almond et al. [19]); mRS3–5 = 0.46 (the same for functional independence); mRS6 = 0.21 (death rate after first stroke according to Leppert et al. [9]); ut2stroke = 0.34 (utility after recurrent stroke according to Ganesalingham et al. [12]); ut_mild = 0.74 (utility after mild stroke according to Ganesalingham et al. [12]); ut_mose = 0.38 (utility after moderate/severe stroke according to Ganesalingham et al. [11]); STAGE = 20 (time horizon in years). The two probabilities, whose value is 0.405, are not supported by any specific reference, but reflect expert opinion.

References


