Value-based procurement of prostheses for total knee replacement

Andrea Messori, Sabrina Trippoli

HTA Section, ESTAR Toscana, Regional Health Service, Firenze, Italy

Abstract

Cost-effectiveness evaluations concerning devices for total knee arthroplasty (TKA) have little impact on real-life management of these devices. This study explored how pharmacoeconomic models can inform the procurement of TKA devices to improve their value for money. Our study included three phases: i) literature search for data of outcome, cost, and device type in TKA; ii) development of a Markov model predicting costs, QALYs, and net monetary benefit (NMB); iii) simulation of tenders aimed at value-based device procurement. Phases 1 and 2 were managed by selecting a single study as the source of data for our analysis. In Phase 3, each TKA device was associated with its values of NMB, and the tender scores were estimated. Finally, the ranking of each device in the simulated tender was determined. We identified a study published in 2016 as our source of data. Five devices were evaluated. For these devices, QALYs were 7.3952, 7.2939, 7.4952, 7.1919, 7.2930; NMB: £142,005, £140,653, £144,184, £138,040, £140,261; tender scores: 64.53, 42.53, 100, 0, 36.15, respectively. We showed that incorporating the principles of cost-effectiveness into the tendering process is feasible for TKA devices. This can maximize the value for money for these devices.

Introduction

In Europe, cost-effectiveness has generally little or no impact on the administrative procurement of implantable medical devices. When procurement involves a class of medical devices with similar characteristics, most European countries employ competitive tenders. These tenders, which are typically run by regional bodies of national health systems, include a formal invitation to vendors for the supply of goods or services. Hospitals belonging to the public health system in this way buy what they need for their activities and, at the same time, fulfil the requirements of legislation. One putative advantage is that this form of public procurement gives priority to products ensuring the best clinical value at the lowest price.

At present, an overall scientific rationale in terms of cost-effectiveness is lacking in this field, inasmuch as tenders are not generally based on any conceptual framework, and are therefore managed through a case-by-case approach. However, an original method has recently been proposed in the field of total hip arthroplasty to apply the principles of value-based procurement.[1]

In the present study, we have applied the above-mentioned method to the procurement of prostheses for total knee arthroplasty (TKA). Evaluating the cost-effectiveness of these devices is recognized to be an important issue;[2-4] the main purpose of our study was to apply the value-based method to a data-set of real life.

Correspondence: Andrea Messori, HTA Unit, ESTAR Toscana, Regional Health Service, Via San Salvi 12, 50135 Firenze, Italy.
Fax: +39-0574-701319
E-mail: andrea.messori.it@gmail.com

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Materials and Methods

Study design

The data of our project were directly extracted from a published cost-effectiveness article,[4] that was considered the source of all information needed for our original methodological experience.

Based on the cost-effectiveness profile of prostheses for knee replacement (expressed as net monetary benefit, NMB), the aim of our study was to calculate a value-based score for each device to be used in the tendering process. This score is aimed at maximizing the value for money of these devices.

The design of our study included a first phase aimed at retrieving cost data and quality-adjusted life years (QALYs)[5] from patients undergoing TKA with various brands of knee prostheses, a second phase in which the best simulation method was identified for modeling outcomes and predicting QALYs, and a third phase where a value-based tender score (defined according to standard tendering equations and adapted to a 0-to-100 scale) was estimated for each device. This allowed us to determine the ranking of each device in the simulated tender. QALYs represent the typical parameter of cost-effectiveness analysis and incorporate an estimate of the length of survival adjusted according to the patient's quality of life (*e.g.* living 4 years at 75% of quality of life is considered equivalent to living 6 years at 50% of quality of life because 3 QALYs are achieved in both cases).

Identification of the source of the data needed for our analysis

Our search, conducted using the PubMed database, was carried out to select the cost-effectiveness study on TKA from which we could retrieve the values of QALYs, net monetary benefit (NMB), and cost for a series of devices (search term: *(cost[titl] OR economic[titl]) AND knee AND (replacement OR arthroplasty OR prosthesis) AND Markov*). Eligible papers from the above search were examined to identify those papers that met the following criteria: i) cost-effectiveness analysis based on Markov modeling; ii) patient population undergoing TKA; iii) evaluation of at least three different brands of TKA device with separate information on costs for individual devices; d) separate presentation of values of QALYs per patient and NMB. Finally, to identify from eligible papers the single article to be used as data source for our analysis we planned to make this decision by consensus among authors.

Pharmacoeconomic analysis, modeling of outcomes and calculation of QALYs

The perspective of our pharmacoeconomic analysis was that of a national health system. Direct costs were included, whereas indirect costs were left out. One criterion for selecting the published study to be used as data source for our analysis was that the selected study had to report a Markov model suitable for calculating the QALYs per patient. As in our previous analysis,[1] in the present study we planned to determine the value of QALYs per patient by directly using the values of QALY reported in the

selected paper or by recalculating these values using the computer program (if publicly available) employed in the selected study or, alternatively, by rewriting the Markov model using the language of a commercial software (Treeage Pro version 11, Treeage Inc, Williamstown, Massachusetts) thus recalculating these values. QALYs are typically applied based on a clinical scenario covering several years; accordingly, our simulation model employed a time horizon of 20 years.

Net monetary benefit

The NMB is defined as follows:[5]

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 predetermined cost-effectiveness threshold (£20,000 as in the study by Pennington *et al.*); the cost of the device is expressed in £; the other treatment-related costs (OTRCs) are represented by a series of items that should be qualitatively the same across all treatments under examination. These OTRCs do not include the cost of the device, but always include the costs, other than the device cost, incurred on the short term (*e.g.* accessories, *etc*). In addition, depending on the specific disease condition under examination and the type of economic information actually available, these OTRCs may also include the costs incurred by the patients on the long term.

Finally, the equation of NMB can also be expressed by replacing the device cost and the OTRC with a single term of negative sign, defined as the sum of the device cost plus the OTRC.

Estimation of tender-based scores

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;[6] its equation is as follows:

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

Results

Identification of the source of the data needed for our analysis

After selecting a total of 50 eligible papers from our literature analysis (date of the PubMed search: 9 November 2017), we selected the study by Pennington *et al.*[4] as our data source. This was in fact the only Markovian study that evaluated the cost-effectiveness profile, expressed in terms of NMB, of a series of brand prostheses for TKA. Five devices (namely, PFC Sigma, AGC Biomet, Nexgen, Genesis2, and Triathlon) were investigated by Pennington *et al.*[4] The horizon was lifetime, the yearly discount rate was 3.5%, and the willingness-to-pay threshold was £20,000 per QALY.

Development of a publicly available version of the Markov simulation software

Since the modeling software employed by Pennington *et al*. was not publicly available, we re-wrote the Markov simulation procedure[8] using the language of Treeage. Our computer program can be downloaded as indicated by Messori.[8]

Estimation of QALYs, NMB, and tender-based scores

For each of the 5 devices, Table 1 shows the information reported in the study by Pennington *et al.*[4] and the results generated by our analysis. As expected, the values of QALYs and NMB, recalculated in our results according to the Markov model[8] and Equation 1, were nearly identical to those originally reported by Pennington *et al.*[4] Table 1 describes also the tender scores that we calculated according to Equation 2.

Discussion and Conclusions

Although studying the cost-effectiveness of TKA devices has an undisputed scientific interest, this type of research has mainly a speculative value and, in practice, is not applied to the current procedures for device acquisition in the real world. More precisely, the results of cost-effectiveness studies on medical devices are reported quite frequently in scientific journals, but the decisions about procurement in real life continue to be based on the *traditional* work of administrative offices (wherein 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 generally 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. Needless to say, the situation of devices for TKA is very similar to that of all the other implantable devices.

The experience described in this paper has a two-fold value. Firstly, while most economic methods of the present paper are similar to those employed in numerous

Table 1. Model parameters for each device and estimated values of QALYs, NMB, and tender score (reference population: men aged 70 years).

	PFC Sigma	AGC Biomet	Nexgen	Genesis 2	Triathlon
Utility after surgery	0.73	0.72	0.74	0.71	0.72
Annual revision rate§	0.31%	0.42%	0.31%	0.37%	0.38%
QALYs per patient*	7.2911	7.2907	7.3919	7.0914	7.1912
Cost per patient (£)	5,900	5,226	5,721	5,799	5,600
NMB per patient (£)	139,923	140,589	142,118	136,030	138,225
Tender score	63.94	74.88	100	0	36.05

§Calculated from the rate at 10 years reported by Pennington *et al.*[4] divided by 10. *QALYs were re-estimated using the Markov model described in Reference [8], while NMB and tender scores were calculated according to Equations 1 and 2, respectively. The values of utility, revision rate, and cost per patient are those published by Pennington *et al.*[4] The cost per patient includes the cost of the device and all treatment-related costs. Other parameters of the model (common to the 5 devices) were: time horizon = 20 years; annual discount rate = 3.5%; death rate at surgery = 0.3%.

cost-effectiveness studies,[4,7] the originality of the present work lies in our attempt to directly link the clinical outcomes with the administrative decisions (namely, the decisions adopted for the procurement of devices). Secondly, as previous research has already pointed out, the use of different simulation models in this disease condition introduces an important bias that increases the heterogeneity of cost-effectiveness results (Chiumente & Messori, unpublished data, 2017). 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 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 Nexgen, followed by the other four devices. Likewise, Nexgen showed the best value of NMB thus indicating that this device has a more favorable cost-effectiveness in comparison with the others. The same result was given also by the tender scores.

It should be noted that the approach based on NMB conveys 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 has a good performance in capturing the differences in effectiveness among different devices and, more importantly, the method succeeds in assigning a *fair* economic value to the increased effectiveness demonstrated by the most effective devices.

When this information about ranking in effectiveness was converted from NMB into the tender score, the scores 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 essentially reflected the same message concerning comparative effectiveness and cost-effectiveness.

Furthermore, it should be recalled that, in the classic analysis based on ICER, only two comparators are directly managed. For example, if A is the innovative therapy and B is the standard therapy (and assuming that all values of cost and quality-adjusted survival are normalised to 1 patient), $ICER_{AvsB}$ is defined as: $ICER_{AvsB} = (cost_A - cost_B) / (QALY_A - QALY_B)$. After this calculation, $ICER_{AvsB}$ is evaluated against the predefined cost-utility threshold (T), (*e.g.* £ 30,000 in the UK or around $100,000 in the US) to decide if using A as opposed to B has a favourable cost-utility (ICER<T) or an unfavourable cost-utility (ICER>T). One limitation is that, while tenders generally evaluate three or more comparators, the equation of ICER manages just a single comparison, *i.e.* only two comparators. This methodological point is discussed more thoroughly in References 1 and 9.

The growing health-care needs and the increase of new and expensive healthcare technologies are a challenge for the sustainability of health systems worldwide.[10,11] Globally, national health systems are currently spending around US 100 dollar billion per year only for anticancer drugs.[11] In this framework, in-hospital expenditures, particularly those concerning drugs and implantable devices, are being increasingly investigated and verified in terms of value for money.

It is well known that, in numerous countries (and particularly in Europe, Australia, and Canada), innovative drugs are systematically evaluated for their cost-effectiveness whereas this does not occur for implantable devices, the cost of which of represents a relevant source of in-hospital expenditure as well. For medical devices, no proof of procurement based on cost-effectiveness emerges from the database of PubMed;[12] this underscores that the approach described herein deserves to be further investigated and applied in a real-world setting.

Our study has shown that, in regard to devices for TKA, the methodology of cost-effectiveness can be successfully incorporated into the practice of in-hospital procurement and competitive tendering. This innovative approach can maximize the health return generated by the expenditure for these devices.

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