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SHORT COMMUNICATION
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Costs and benefits in patients with NYHA class III heart failure treated with CardioMEMS in Italy

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ABSTRACT

Background: CardioMEMS is a device suitable for telemedicine that is currently being evaluated by the Regional Health Technology Assessment (HTA) Committee of Tuscany. Two detailed HTA reports are available in the specialized literature, the results of which need to be transferred to our regional setting. These decisions in Tuscany are made by the so-called Centro Operativo HTA.
Aim: To validate, with local cost-effectiveness data, the decision on CardioMEMS that will be made in the Tuscany region.
Methods: Two detailed international HTA reports were rearranged and adapted to our regional setting to generate a simplified analysis that could form the basis of our decision. Two willingness-to-pay (WTP) thresholds of €20,000/quality-adjusted life year (QALY) and €50,000/QALY were considered.
Results: Based on epidemiological and regulatory information, the target population in Tuscany for this device is 166 cases. The value-based price of CardioMEMS is estimated to be €4,332 and €16,662 at WTP thresholds of 20,000/QALY and 50,000/QALY, respectively. Its current price in Italy is €12,000.
Conclusion: In our region, the introduction of CardioMEMS is likely to be gradual, around 50 patients/year (or €0.60 million/year at current price). This example highlights the need to adapt the information published in the international literature to the local context in which the approval decision is made. In this context, simplified analyses are easier to apply than complex Markov models.

Keywords: Heart failure, MitraClip, NYHA class, Telemedicine, Value-based price

The introduction of telemedicine in cardiology raises several complex issues, particularly in terms of organization and cost-effectiveness. A typical example is CardioMEMS, a device designed to help cardiologists monitor heart failure patients with certain characteristics (namely, New York Heart Association [NYHA] class III and at least one hospitalization in the past 12 months). CardioMEMS is an interesting example of the application of telemedicine in cardiology. Thanks to the implantation of this device, these patients can be remotely monitored through daily measurements of pulmonary artery pressure; this allows for better management of these patients, since medical therapy can be more strictly individualized and cases of deterioration can be detected earlier.

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As shown in the pivotal studies evaluating CardioMEMS (1,2), the main benefits experienced by patients monitored by this device include an improvement in quality of life and a reduction in hospital admissions; on the other hand, no improvement in overall survival has been demonstrated (3). Regarding the benefit in terms of reduced hospitalizations, the recent randomized MONITOR-HF study (1) reported a 44% reduction in hospitalizations over 48 months: specifically, there were 117 hospitalizations in the CardioMEMS group (equivalent to 0.381 per patient per year) vs. 212 in the control group (equivalent to 0.678 per patient per year; hazard ratio, 0.56; 95% confidence interval [CI], 0.38 to 0.84; p = 0.0053); the mean age in the overall population was 69 years (interquartile range [IQR] 61 to 75). The absolute reduction was therefore 0.678 − 0.381 = 0.297 hospitalizations per patient per year, which we can round to 0.30 hospitalizations/patient over 1 year (or 1.20 hospitalizations/patient over 4 years). Although statistically significant, the absolute magnitude of this benefit is quite small, which increases the need for detailed economic analysis. The other major benefit observed in MONITOR-HF was an improvement in quality

of life at 12 months of 7.13 points (95% CI, 1.51 to 12.75) in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score, a quality-of-life tool that is unfortunately rarely used in cost-effectiveness studies. Regarding quality of life, if one refers to the other randomized trial focused on CardioMEMS (the CHAMPION trial (2), in which quality of life was expressed as utility), the incremental benefit of CardioMEMS at 12 months is approximately 0.10 quality-adjusted life years (QALYs; difference 0.653 minus 0.547; data from Table 1 of reference 2), which translates into 0.40 QALYs at 4 years; the mean age in the overall population was 61.5 years. The cost of CardioMEMS implantation is approximately €19,000 per patient (device cost of €12,000 plus implantation cost of €7,000; data from references 4 and 5). This cost information is valid for the European countries considered in the two economic analyses (including Italy). Finally, the assessment of the budget impact and cost-effectiveness of this device can be based on a time horizon of 48 months, as suggested by two analyses published by Cowie et al (4,5).

We have applied the main parameters of the above economic analyses to the Italian public healthcare setting. For this purpose, the clinical benefit of 0.40 QALYs/patient can be translated into an economic benefit of €8,000/patient, based on a conservative willingness-to-pay (WTP) threshold of €20,000/QALY. Similarly, since the cost of one hospitalization is currently valued at €3,052 according to the Italian diagnosis-related group (DRG) 127 (5), the avoidance of 1.2 hospitalizations can be valued at €3,662. From the perspective of a neutral budget impact, the above parameters can be easily interpreted by assuming that all costs per patient (estimated as implantation cost of €7000/patient plus device cost) should be offset by all benefits, which in turn consist of a gain of 0.40 QALY/patient (valued at €8,000 as mentioned above) plus the avoidance of 1.2 hospitalizations per patient (valued at €3,662).

Therefore, if the cost of CardioMEMS is chosen as the unknown, the equation becomes

$$(\text{device cost}) + €7{,}000 = €8{,}000 + €3{,}662$$

Therefore, according to the abovementioned WTP threshold of €20,000/QALY, the value-based cost of CardioMEMS is €4,662, which in fact determines a neutral budget impact. On the other hand, if the WTP threshold is set at €50,000/QALY (and the gain of 0.40 QALYs is consequently valued at €20,000), the above equation can be rearranged as follows:

$$(\text{device cost}) + €7{,}000 = €20{,}000 + €3{,}662$$

which results in a value-based cost for CardioMEMS of €16,662.

Finally, if we reverse the above calculations and consider the incremental cost-effectiveness ratio (ICER) as the unknown, the equation becomes

$$€12{,}000 + €7{,}000 = 0.40 \times \text{ICER} + €3{,}662$$

where €12,000 is the current price of CardioMEMS. In this case, the ICER of CardioMEMS is estimated to be €38,435/QALY, which is below the usual WTP thresholds but in the upper range of acceptability.

We have attempted to estimate the total budget impact of CardioMEMS in a large jurisdiction such as the region of Tuscany (3,766,000 inhabitants). The availability of this device in our hospitals was requested from regional cardiology units. The prevalence of chronic heart failure in Tuscany is about 2.04%, according to the regional frequency of DRG 127, which was 7,547 cases in 2021 (personal communication, Francesca Collini, Agenzia Regionale di Sanità, Regione Toscana: 7,547 cases of DRG 127 in 2021). Of these, 1,339 (17.7%) had at least one hospital admission in the previous 12 months. Therefore, assuming that NYHA class III represents 12.4% of these subjects (according to Table V of reference 7), the total population of candidates for the use of CardioMEMS in Tuscany is 166 cases.

In terms of budget impact, assuming that the device is used in all of these 166 cases, the total investment in Tuscany would be €0.77 million at the budget-neutral price of €4,332 per device or €1.99 million at the current price of the device or €2.76 million at the price of €16,662. Of course, in our regional setting, the introduction of CardioMEMS is likely to be gradual, about 50 patients/year according to the estimate of the Tuscan cardiologists. For comparison, the total annual expenditure on medical devices in Tuscany in 2021 was €501 million.

There are two common drawbacks between our economic analysis and those published by Cowie et al (4,5). First, there is an organizational impact in cardiology units adopting CardioMEMS, as remote patient monitoring implies the use of staff resources that need to be more accurately quantified. Second, the above estimate of 12.4% of NYHA class III patients among the CardioMEMS candidates (an information used in our analysis) may be an underestimate, as the subgroup of patients with at least one admission in the last 12 months may include more class III patients than the 12.4% found by Pradelli et al in the overall heart failure population (6,7). Finally, because the initial investment to purchase the device is very large, a disadvantage is that in patients who drop out or die early after implantation, the full cost of the device would be paid even though the clinical benefit is negligible or much less than predicted by the model. In these cases, reimbursement for treatment failure (regardless of its cause), specifically addressed in the purchase contract, could help improve the otherwise borderline cost-effectiveness of the device.

In conclusion, our short report highlights the high level of complexity involved in making decisions about medical devices suitable for telemedicine application in a universal healthcare system. In our opinion, while complex modeling of all relevant variables is certainly appropriate from a scientific point of view (4,5), the average reader can be profitably assisted by simplified and easy-to-understand analyses that have the advantage of producing essentially the same results as the complex models. Our experience with the approval of CardioMEMS in Tuscany is in line with these considerations. Despite the existence of a Health Technology Assessment (HTA) committee ("Centro Operativo HTA") specifically dedicated to the approval of implantable devices in the region of Tuscany and the availability of two

international HTA reports on CardioMEMS focused on the European setting (4,5), reaching a decision on this difficult issue remains complex. There are at least two reasons for this: first, the lack of a WTP threshold officially recognized by the local health system hampers the ability of local HTA committees to make decisions for the local setting. Second, HTA reports that are entirely based on Markovian simulations pose a difficult challenge as to whether the conclusions of the simulation study can be transferred to local practice and whether their scientific basis is sufficiently sound to support a demanding decision. In this context, this example shows that a simplified report summarizing the main points of an HTA evaluation can play a useful role in local decision-making.

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