

On the Cost-effectiveness of Dabigatran

Sobre el coste-efectividad del dabigatrán

To the Editor,

The introduction of new oral anticoagulants for the prevention of thrombotic events in nonvalvular atrial fibrillation continues to be a subject of debate. One controversial issue is its cost. In a recent issue of the *Revista Española de Cardiología*, González-Juanatey et al.¹ reported that dabigatran was cost-effective compared with vitamin K antagonists. However, my attention has been drawn to certain aspects that I would like to examine in detail.

First, the authors disclose conflicts of interest involving the manufacturer of dabigatran and expressly state that these interests did not influence the results reported in their article. However, Valachis et al.² demonstrated that studies in which there are conflicts of interest involving pharmaceutical companies demonstrate that the therapies being examined are cost-effective more often than those in which there are no financial relationships.

Cost-effectiveness studies depend on the costs taken into account and on the effectiveness assigned to each arm of the comparison.³ González-Juanatey et al. estimated the annual costs of vitamin K antagonists anticoagulation therapy with international normalized ratio monitoring in capillary blood to be 378.00 euros with good control and 462.31 euros with poor control. It is surprising that these costs are higher than those reported in the United Kingdom.⁴ Even more surprising, however, is that one of the authors fails to recall that, in 2008, he published a study,⁵ financed by the Spanish social security system, in which the mean cost of therapy per patient per year was 135.14 euros.

Cost analyses can also be carried out by calculating the incremental cost-effectiveness. We calculated the incremental cost-effectiveness of dabigatran vs vitamin K antagonists to assess its cost-effectiveness in our health area.

We work with a decentralized system for international normalized ratio determination in capillary blood, with sample collection in 32 units and electronic transfer of the results to the referral center. The dosages are sent back following validation by the hematologist. In our patient population, 69% of the international normalized ratio tests performed are within the therapeutic range.

We have 5843 patients receiving anticoagulation therapy, 2320 (40%) due to nonvalvular atrial fibrillation. If we calculate a mean dose of 14 mg per week,⁵ the annual cost of the medication is 124 229.50 euros. The cost of international normalized ratio monitoring test is fixed at 2.80 euros per determination, and includes test strips, monitoring systems, and computer support. In 2011, we performed 84 123 determinations (mean number of determinations per patient per year, 14.5), for an annual cost of 235 554.40 euros.

At the referral center, a hematologist and 2 nurses evaluate the results throughout half of the working day. The sum of the time devoted to monitoring in the peripheral centers would be equivalent to a full working day. Only members of the nursing staff are assigned to this task. With this arrangement, the cost in personnel was 60 075.50 euros per year. We added 8757.50 euros corresponding to costs incurred by other entities, as did Navarro et al.⁵ in their study.

Thus, the annual cost of treatment with vitamin K antagonists in our health area is 428 606.90 euros (73.35 euros per patient). The annual cost of dabigatran is 1106.84 euros, after a discount of 7.5%. This results in an incremental cost per patient per year of 1033.49 euros.

The annual number of patients needed to treat to reduce an event was determined in accordance with the RE-LY (Randomized Evaluation of Long Term Anticoagulant Therapy) trial using a risk calculator (<http://ulan.mede.uic.edu/cgi-bin/nntcalc.pl>). The number of patients needed to treat to prevent a disabling stroke was 294.1 patients with a dose of 150 mg/12 h and 1666.6 with a dose of 110 mg. Thus, the incremental cost-effectiveness required to prevent a disabling stroke proved to be 303 949.23 euros with the 150 mg dose and 1 738 847.11 euros with the 110 mg dose. This cost was compared with the table of indemnities for motor vehicle accidents,⁶ which serves as a reference for judges when evaluating injuries. Thus, in 2012, the death of a 71-year-old patient (mean age in the RE-LY trial) is valued at up to 167 188.22 euros, and the costs corresponding to sequelae would not reach 200 000 euros for all the concepts, including non-material damage.

In view of the above, we do not consider dabigatran to be cost-effective for the prevention of clinically significant thrombotic events in a health area with similar technology for monitoring oral anticoagulation therapy. Cost-effectiveness studies should be carried out by independent organizations for subsequent evaluation by the Spanish health care system, not by the pharmaceutical companies themselves.

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REFERENCES

- González-Juanatey JR, Álvarez-Sabin J, Lobos JM, Martínez-Rubio A, Reverter JC, Oyagüez I, et al. Análisis de coste-efectividad de dabigatrán para la prevención de ictus y embolia sistémica en fibrilación auricular no valvular en España. *Rev Esp Cardiol*. 2012;65:901-10.
- Valachis A, Polyzos NP, Nearchou A, Lind P, Mauri D. Financial relationships in economic analyses of targeted therapies in oncology. *JCO*. 2012;30:1316-20.
- Avorn J. The relative cost-effectiveness of anticoagulants: obvious, except for the cost and the effectiveness. *Circulation*. 2011;123:2519-21.
- Pink J, Lane S, Pirmohamed M, Hughes DA. Dabigatran etexilate versus warfarin in management of non-valvular atrial fibrillation in UK context: quantitative benefit-harm and economic analyses. *BMJ*. 2011;343:d6333.
- Navarro JL, César JM, Fernández MA, Fontcuberta J, Reverter JC, Gol-Freixas J. Tratamiento anticoagulante oral. Estudio coste/beneficio. *Rev Admin Sanit*. 2008;6:525-42. Available at: <http://www.elsevier.es/sites/default/files/elsevier/pdf/261/261v6n3a13127955pdf001.pdf>
- MEyC. Resolution dated 24 January 2012. Available at: <http://www.boe.es/boe/dias/2012/02/06/pdfs/BOE-A-2012-1780.pdf>

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