

Cardiac Resynchronisation Therapy is Cost Effective

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There is robust evidence that cardiac resynchronisation therapy (CRT) is highly cost effective across a range of health systems, including those with robust evaluation processes.¹⁻⁶ In the United Kingdom, following an independent academic review, the National Institute for Health and Clinical Excellence considered the device to be approximately 95% likely to be cost effective compared to optimal medical therapy alone at a willingness-pay of £30 000 per quality-adjusted life year (QALY).⁶ As a result, CRT is recommended for use, in patients with heart failure, left ventricular systolic dysfunction with evidence of dyssynchrony, and moderate or severe symptoms that persist or recur despite optimal medical therapy.⁶ In this issue of *Revista Española de Cardiología* Callejo et al consider the incremental cost-effectiveness of CRT alone and CRT with implantable cardioverter defibrillator (CRT-ICD) compared to standard care in the Spanish healthcare setting.⁷ The results from this study yield much higher incremental cost-effectiveness ratios (ICERs) than previous work and may lead people to question whether this is an appropriate resource use. Given these findings we must consider: why is the Spanish analysis so different?

CRT must have the same effects on cardiac function and symptoms in Spain compared to other similar health care systems, so the differences must

arise either because of different cost structures in Spain, or the model is wrong. Having reviewed the published version of the paper, we have found a number of questionable assumptions and data inputs which lead to, in our view, inappropriately pessimistic results.

The utility values used in this model differ considerably from utilities used in other models, including our own work using individual patient data from 12 European Countries (including Spain) in the CARE-HF trial.² The “utilities” used to populate the model used by Callejo et al were not based on trial results, which is protected from bias by randomisation in the estimation of treatment related effects, but instead used observational data⁷ collected using a visual analogue scale, which the authors correctly acknowledge is far from ideal and differs from those based on results from the EQ-5D index.⁸ This leads to substantially lower benefits in terms of QALYs gained compared to previous estimates.^{2,6} The authors also assume that patients remain in the functional class that they achieve at 18 months, when we can expect relative deterioration in the non CRT patients during longer-term follow-up.

The relative risk for sudden death for CRT compared to optimal pharmacological therapy is presented as 0.91 (confidence interval, 0.6-1.38), but published results from the CARE-HF estimate a hazard ratio of 0.54, (95% confidence interval, 0.35-0.84; $P=.005$).⁹ This under-estimation of the effects of CRT on sudden death reflect the use of a meta-analysis¹⁰ that excluded the longer-term follow-up data from CARE-HF and included studies comparing CRT-ICD with implantable cardioverter defibrillator alone; a comparison that might be expected to show no CRT advantage. Moreover, meta-analyses that combine data from short and long-term studies may not be appropriate. The risks and complications of implantation are observed mostly in the first few months of implantation but the benefits are acquired over a much longer period. CARE-HF has, by far, the longest term follow-up of all the randomised trials of CRT and is the only large trial unconfounded by a high rate of cross-over and not stopped prematurely.¹¹

As a result of the above findings the estimates of the potential benefits of CRT are much lower than

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robust analyses based on individual patient data from the CARE-HF trial.^{1,2}

The other major difference arises in estimates of cost. The absolute and incremental costs are much higher than previous estimates from the United Kingdom, Nordic countries and the United States. We accept that the costs to the Spanish healthcare system will differ from other countries but we are concerned about potential double-counting. For instance, the cost of implanting a CRT device is not clearly stated but that for CRT-ICD is given as €12 066, which appears to be additional to the cost of the device itself (€4257 for CRT and €20 294 for CRT-ICD) and an hourly charge for operating room time and other costs of medical and nursing care. The total cost of implantation may have exceeded €20 000 for CRT and €40 000 for CRT-ICD, which is about twice that estimated in other analyses.

The work by Callejo et al may lead some to question whether CRT should be reimbursed in Spain. With health care expenditure cuts looming, relatively new and expensive technologies could be a target. This would, in our opinion, be a grave mistake if applied to CRT based on the model presented in this issue.

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