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Editorial

The price and value of implantable cardioverter defibrillators in hypertrophic cardiomyopathy

Yang Chen [a,b,c], Constantinos O'Mahony [a,c,*]

[a] Institute of Cardiovascular Science, University College London, Gower St, London WC1E 6BT, United Kingdom
[b] Department of Health Policy, The London School of Economics and Political Science, United Kingdom
[c] St Bartholomew's Hospital, London EC1A 7BE, United Kingdom

Hypertrophic cardiomyopathy (HCM) came to prominence in 1958 when Donald Teare described in the British Heart Journal its typical pathological features in 8 patients who died suddenly. The excessive risk of sudden cardiac death (SCD) dominated the early literature and contemporary 21st century studies suggest that the SCD rate is approximately 1% per year [1]. Ventricular arrhythmias are the primary cause of SCD and the development of the implantable cardioverter defibrillator (ICD) in 1980 was a significant milestone. Since ICDs were approved for human use in 1985, the technology has improved, thoracotomy and abdominal implants have been abandoned and devices are now inserted under conscious sedation as a day case procedure. Subcutaneous ICDs represent the latest iteration of this technology and are particularly attractive as they avoid intracardiac complications [2].

Even though a randomised trial has not been conducted, observational data show that HCM patients with an ICD are highly unlikely to die suddenly, and many receive appropriate ICD shocks. Based on this information, the 2003 joint ACC and ESC guidelines recommended a primary prevention ICD in patients with high risk features [3]. The nature of the risk assessment evolved in subsequent guidelines, but ICDs remained the mainstay of SCD prevention [1,4]. Approximately 30% of HCM patients are candidates for a primary prevention ICD [5].

An early economic analysis of primary prevention ICDs in HCM concluded that ICDs were cost effective when used in high risk patients [6]. However, the complicated economic model employed was limited by the source data used to determine the quality of life (QoL) attached to each individual health state. Specifically, only one quarter of the QoL source data originated from patients who actually suffered from the condition.

In this issue, Magnusson and Wimo examined the cost-effectiveness of an ICD among HCM patients with the same economic modelling principles but used a simpler model, with fewer assumptions [7]. Only two health states were considered: 'alive' and 'dead' and their simulated cohort was aged 52 years at the start of the analysis. The authors used a societal perspective which is novel in this context, as it considered the wider economic implications of preventing SCD and keeping people alive and in employment. Their study showed that an ICD was both cheaper and better in terms of gained QALYs than conservative management, demonstrating the positive economic impact that ICDs may have in addition to saving lives. This hopefully reflects the experience of many centres treating HCM patients who are relatively young, with few comorbidities and potentially long life expectancies. Although the base-case simulation was over a 12-year period, it is noteworthy that over a longer time horizon of 24 years the results were largely unchanged. The decision on a 12-year period seems driven in part by the desire to ensure that extrapolation of data is minimised. This obviates a weakness of lifetime economic models where forecasted benefits, decades into the future, rely on an increasing number of assumptions. We commend the authors' decision to choose such a pragmatic model to answer their research question in a manner that can convey a powerful and clear message.

Model simplicity affords strengths but also limitations. In any economic analysis, the concept of utility and Quality Adjusted Life Years (QALYs) of different health states have a significant impact on the cost-effectiveness of the treatment studied and its headline incremental cost effectiveness ratio (ICER). Here, the concept of one QALY is that of one year spent in perfect health. In this paper, the authors used an arbitrary multiplier of 0.8 to model for patients with HCM who do not have perfect health. This meant that patients in the 'alive' health state did not have a QALY of 1.0 but rather a number generated from the Swedish population reference range, adjusted for age, and the arbitrary 0.8 multiplier. Furthermore, there was no modelling to account for the impact on quality of life from device shocks (either appropriate or inappropriate) and other relevant device-related events but these may be of less importance given that ICDs confer a mortality benefit in high risk patients. If quality of life assessment were to be introduced, this could be done either through use of a time trade-off method of either experts or healthy volunteers, or by directly eliciting QoL from patients themselves, through patient reported outcome measures [8]. Given that the study team used data from patients with HCM and an ICD to obtain the 0.8 multiplier, future work in collecting more detailed PROMs could allow the development of a more complex model, including what the quality of life of HCM patients without an ICD would be, as well as modelling for other important clinical events [9].

Although not explicitly addressed by the authors, one other important factor is the idea of the simulation 'cycle length' – that is the

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* Corresponding author at: St. Bartholomew's Centre for Inherited Cardiovascular Disease, St Bartholomew's Hospital, London EC1A 7BE, United Kingdom.
E-mail address: drcostasomahony@gmail.com (C. O'Mahony).

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amount of time spent in each state before the next round of simulation. There will be a clear difference in the probability of moving health states between a monthly versus yearly cycle-length. Once more, compromises between simplicity and granularity (with more assumptions though potentially more accurately reflecting real-life complexity) are key considerations [10].

For any healthcare system, the decision to offer a treatment is not simply made on cost-effectiveness alone. Distributive justice, budget constraints and the societal willingness to pay are important considerations for health policy makers when determining system-wide funding allocations. The value of health economic analyses is in re-framing clinical interventions to either support the status quo or to change it. Cardiologists need to be able to assess current and emerging interventions to allow external agencies and funders understand the benefits of treatments beyond those found in clinical trials or registries. As we move toward increasingly digitalised and commercialised healthcare, studies such as the one carried out by Magnusson and Wimo [7] will protect our patients' access to interventions that are of benefit not only to them but to the wider healthcare system.

References

[1] P.M. Elliott, A. Anastasakis, M.A. Borger, M. Borggrefe, F. Cecchi, P. Charron, et al., 2014 ESC Guidelines on diagnosis and management of hypertrophic cardiomyopathy: The Task Force for the Diagnosis and Management of Hypertrophic Cardiomyopathy of the European Society of Cardiology (ESC), Eur. Heart J. 35 (2014) 2733–2779.

[2] P.D. Lambiase, M.R. Gold, M. Hood, L. Boersma, D.A. Theuns, M.C. Burke, et al., Evaluation of subcutaneous ICD early performance in hypertrophic cardiomyopathy from the pooled EFFORTLESS and IDE cohorts, Heart Rhythm. 13 (2016) 1066–1074.

[3] B.J. Maron, W.J. McKenna, G.K. Danielson, L.J. Kappenberger, H.J. Kuhn, C.E. Seidman, et al., American College of Cardiology/European Society of Cardiology Clinical Expert Consensus Document on Hypertrophic Cardiomyopathy: A report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents and the European Society of Cardiology Committee for Practice Guidelines, Eur. Heart J. 24 (2003) 1965–1991.

[4] B.J. Gersh, B.J. Maron, R.O. Bonow, J.A. Dearani, M.A. Fifer, M.S. Link, et al., 2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, Circulation 124 (2011) 2761–2796.

[5] C. O'Mahony, M.M. Akhtar, Z. Anastasiou, O.P. Guttmann, P.A. Vriesendorp, M. Michels, et al., Effectiveness of the 2014 European Society of Cardiology guideline on sudden cardiac death in hypertrophic cardiomyopathy: a systematic review and meta-analysis, Heart 105 (2019) 623–631.

[6] J.J. You, A. Woo, D.T. Ko, D.A. Cameron, A. Mihailovic, M. Krahn, Life expectancy gains and cost-effectiveness of implantable cardioverter/defibrillators for the primary prevention of sudden cardiac death in patients with hypertrophic cardiomyopathy, Am. Heart J. 154 (2007) 899–907.

[7] P. Magnusson, A. Wimo, Health economic evaluation of implantable cardioverter defibrillators in hypertrophic cardiomyopathy in adults, Int.J Cardiol. (2020)pii: S0167-5273(19)35600-1.

[8] N. Ozasa, T. Morimoto, Y. Furukawa, S. Shizuta, K. Nishiyama, T. Kita, et al., Effects of ICD implantation on quality-adjusted life years in patients with congestive heart failure, Int.J Cardiol. 123 (2008) 213–216.

[9] P. Magnusson, S. Morner, F. Gadler, J. Karlsson, Health-related quality of life in hypertrophic cardiomyopathy patients with implantable defibrillators, Health Qual. Life Outcomes. 14 (2016) 62.

[10] Y. Chen, M. Gomes, J.V. Garcia, R.J. Hunter, A.W. Chow, M. Dhinoja, et al., Cost-effectiveness of ablation of ventricular tachycardia in ischaemic cardiomyopathy: limitations in the trial evidence base, Open.Heart 7 (2020), e001155.

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