BHRS commentary on NICE EnduraLife powered CRT-D devices for treating heart failure: Medical Technologies Guidance MTG33, March 2017

Introduction

BHRS supports the view of the Medical Technologies Committee that device longevity is important in selecting cardiac resynchronisation defibrillator (CRT-D) devices, chiefly because of complications associated with device replacement.

Whilst BHRS accepts the majority of the evaluation's findings, we have serious concerns that the resulting conclusions expressed in the guidance have understated and in places ignored, important reservations expressed by the External Assessment Centre (EAC), ourselves, and others.

Our concerns with the Guidance are as follows:

1. Battery chemistry is not the only determinant of longevity
   The appraisal was sponsored by Boston Scientific Inc. and consequently the Guidance focuses on its proprietary "EnduraLife" battery chemistry. As pointed out more than once by the EAC *"battery capacity is an important factor … but it does not act in isolation."* Current consumption is the other side of the equation and many technical factors influence this (see below). In recent years, competing manufacturers have themselves incorporated new batteries and leveraged these factors to reduce consumption and significantly improve device longevity. *We feel it is inappropriate to highlight one kind of battery chemistry when the issue is overall device longevity*.

2. The study's findings unavoidably pertain to obsolete models
   The six retrospective observational studies included in the assessment (two of which were abstracts of conference *poster* presentations, not peer-reviewed papers) included models implanted almost exclusively up to 2010. Even the "recent generation" models in the Landolina 2015 study were implanted in 2007-2010. They also include small patient numbers. We accept that during the period 2005-10 the "EnduraLife" battery technology in Boston Scientific CRT-D devices gave them a significant longevity advantage over competitors and set a new bar in the industry. However, as stated by the EAC, *"the main weakness of the evidence is that it appears to relate to devices no longer on the market due to the rapid turnover of new models of the technology."* Likewise, *"It is likely that different manufacturers have all undertaken CRT-D development focussed on numerous CRT-D components such that devices marketed today may have better longevity than their predecessors studied in the included longevity studies."*

   Our experience is that this is indeed the case. Since 2010, competing manufacturers have also largely switched to new battery chemistry with increased capacity. Meanwhile, technical innovations have been introduced to reduce current consumption. For example, Medtronic capacitors now require less frequent "reform" charges each of which can consume ~1 month of battery life. Other innovations cut battery drain due to telemetry and the background "housekeeping" current, and algorithms to minimise unnecessary right ventricular pacing.

   As a result, there is no longer a large disparity between current Boston Scientific CRT-D device longevity and that of competitors. Longevity estimates of competitors' post-2010 models, using observed real-world current drain (based on remote follow up of 10,000s of patients) are now similar to those of Boston Scientific models. It is noteworthy that the warranties for current models from Boston Scientific (6 yrs), Medtronic (6 yrs), St Jude (6 yrs), and Livanova (7yrs) are similar.

This retrospective "snapshot" resulting from the timing of the current evaluation has shown the sponsor in a favourable light. This is analogous to that of other major recent advances in CRT-D technology, such as remote follow up (reducing clinic visits and permitting early detection of faults), full-body MRI conditionality, and quadripolar LV leads (greatly reducing re-interventions and associated complications). Each advance, introduced by one manufacturer, became standard across the industry within 1-3 years. A critically timed appraisal may have favoured one manufacturer, yet appeared at a time by which others had matched or bettered its technology.

Despite these considerations and the advice of the EAC, the consultation document concludes "the recent advances in CRT-D technology are unlikely to negate the benefits of EnduraLife-powered battery performance on device lifespan compared with other devices." *This assertion is unsubstantiated and we strongly contest it.*

3. The cost implications are not compelling
   The time horizon in the initial analysis happens to significantly favour Boston Scientific models over comparators, as most of the former would not have required replacement, while most of the latter would. As noted by the EAC, *"the choice of a 6 year time horizon potentially exaggerates the cost saving of a slightly longer lasting device."* NICOR data indicates that CRT-D patient survival >6 years is common. Horizons of 4 or 8 years would have given very different results. Unfortunately, the rapid changes in device technology mean that extension of the cost model beyond 8 years (when most implants will have replaced by models 2-3 generations more advanced), cannot be realistic. Even accepting the model, the estimated savings of £6m in the first 5 years is not overwhelming; while the introduction of national procurement calls the relevance of the cost model into doubt.

4. Longevity is far from the only attribute to be considered in device selection
   We do endorse the relevance of device longevity on clinical grounds (fewer complications associated with replacement). However, many other features (such as those listed above) have clinical implications. Now, and in the future, they must be taken into account in an overall procurement strategy and in device selection for individual patients.

   Most importantly, it is essential to maintain a degree of diversity in procurement of devices. As currently written, the current guidance might be seen as a wholesale endorsement by NICE of Boston Scientific CRT-D products to the exclusion of competitors. However, over the last two decades all three major manufacturers have had ICD/CRT-D generators and/or leads subject to major advisories and recalls, sometimes years after the models came to market. Although clinical harm has statistically been tiny in comparison to the therapeutic benefit, these advisories have incurred distress for patients and a huge workload for centres. We therefore regard it essential to maintain diversity in procurement; to "put all one's eggs in one basket" would be a mistake and potentially expose patients to harm.

Summary

The improvement in CRT-D device longevity introduced by Boston Scientific has been very welcome and set a new bar, which the rest of the industry has followed and largely met. While acknowledging the excellent work of the Medical Technologies Committee, we believe that the guidance can only be applied with great caution to the choice of CRT-D devices currently on the market. We are concerned that the conclusions expressed in the Medical Technologies Guidance 33 are oversimplified and possibly even misleading in relation to current models and observations of obsolete models may inform inappropriate and potentially risky procurement decisions for years to come.

This document was prepared on behalf of BHRS Council and has been read and approved by its members.