British Cardiovascular Society

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BCS Guidelines and Practice Committee Reviews

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BCS comment on: Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120)

The British Cardiac Society (BCS) welcomes the review of TA95 and TA120. The combination of both into a single document is a positive step. The review is thorough and utilises all of the relevant evidence in the literature. Many notable improvements have been made to the guidelines. However, there are a couple of recommendations that fall outside of standard practice and will come as a surprise to the majority of clinicians who work in this field.

BCS would like to highlight some concerns regarding the recommendations for devices in patients with LVSD (EF<35%). We also have minor comments to make regarding the format of the document itself.

Significant concerns:

A) Recommendation for no device therapy in patients with LVSD <35%, QRS<120msec, NYHA I-III.

1) The recommendation to not implant ICDs in patients with EF<35%, QRS<120msec is out of line with clinical opinion in the UK.
2) ICDs are recommended for this group in both American guidelines (Epstein et al, J Am Coll Cardiol 2008;51:el-e62) and European guidelines (McMurray et al. European Heart Journal 2012;33;1787-1847).
3) There is no evidence to support the assertion that patients in this category do not benefit (in terms of prognosis) from implantation of an ICD. Indeed the randomised controlled trials clearly demonstrate a survival benefit in this cohort. Consensus amongst clinicians is that use of QRS<120msec to differentiate those patients with EF<35% eligible for ICD implantation is fundamentally flawed and not evidence based.
4) The cost-effectiveness analysis submitted by the manufacturers relating to EF<35%, QRS<120msec is very confused. Patients with QRS<120msec cannot by definition have LBBB or non-LBBB. Therefore QRS <120msec 'LBBB' and 'Non-LBBB' can't have different ICERs. The committee acknowledge this issue regarding the cost effectiveness analysis yet appear to use these data to exclude ICD implantation (despite ICERs < £30000 and comparable to devices recommended in other patient groups).
5) The committee are aware that subgroups of patients within this cohort are at highest risk and therefore benefit most from ICD implantation e.g. men <60yrs.

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Specific guidance could be made recommending implantation in this sub group. The risk factors of age and gender are used to guide intervention in other circumstances e.g. anticoagulation in Atrial Fibrillation using the CHA2DS2VASc scoring system (see NICE Atrial Fibrillation guidance published for consultation 14.1.14).

We do however recognise difficulties in using gender and age when writing guidance. A compromise might be along the lines of:

'ICD implantation is not routinely recommended in patients with NYHA I-III, EF<35%, QRS<120msec however may be considered in those patients where it is deemed clinically appropriate.'

BCS strongly suggests that the committee reconsider the recommendation not to implant ICDs in patients with EF<35%, QRS<120msec.

B) Recommendation for CRT-P rather than CRT-D in patients with NYHA III heart failure, LVSD<35% and LBBB>150msec

1) It seems perverse to implant a CRT-P device into the cohort of patients that have repeatedly shown the most benefit from CRT-D in clinical trials, whilst offering CRT-D to patients at less risk of sudden arrhythmic death. This is the exact group of patients that benefit most from CRT-D and were targeted for this therapy in the previous NICE guidance.
2) The committee acknowledge that differentiation of NYHA II and NYHA III can be difficult for the clinician. Patients also move between these two NYHA classes during disease progression. The decision to implant a CRT-P or a CRT-D will therefore prove problematic and open to interpretation.

BCS strongly suggests that the committee reconsider the recommendation not to implant CRT-D in patients with EF<35%, QRS>150msec, LBBB and NYHAIII symptoms.

C) Recommendation for ICD rather than CRT-D in patients with NYHA I-II heart failure, LVSD<35% and LBBB 120--149msec
Similarly to above, it is unclear why CRT is not recommended for patients in this cohort. Firstly, NYHA II symptoms are often difficult to distinguish clinically from NYHA III (where CRT-D is an option). Secondly, MADIT-CRT provides clear evidence of clinical benefit in this group. Thirdly, the calculated ICER for CRT-D appears less than that in NYHA III where CRT-D is recommended.

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Minor Comments

1) We welcome the combination of ICD and CRT recommendations into a single guideline. The proposed format could however be improved as the guideline is quite cumbersome and difficult to read in its current state. A summary table of recommendations for the primary prevention cohort with LVSD (EF<35%) would be helpful. E.g.

	NYHAI	NYHAII	NYHAIII	NYHAIV
QRS<120msec				
QRS 120-149msec (LBBB)				
QRS 120-149msec (Non-LBBB)				
QRS >150msec (LBBB)				
QRS >150msec (Non-LBBB)				

2) The description of three populations of patients is unhelpful to the clinician. There is significant overlap between 'Population 2' (LVSD and heart failure) and 'Population 3' (LVSD and heart failure and risk of sudden cardiac death). We would recommend removal of this classification.

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on behalf of BCS