A formal statement from the British Heart Valve Society in response to publication of NICE Guidance NG208 Heart Valve Disease Presenting in Adults: Investigation and Management

Introduction

As the official professional healthcare society concerned with all aspects of care relating to patients with heart valve disease (HVD), the British Heart Valve Society (BHVS) welcomes publication of the final guidance from NICE on the investigation and management of patients with HVD.[1]

Soon after our Society was formed a decade ago, we began conversations with senior clinicians in the NHS about the need for a comprehensive national evaluation of care for patients living with heart valve disease. We believed that patients with HVD deserved a document to transform (improve) HVD services in the same way that the creation of the National Service Frameworks transformed care for patients with coronary heart disease two decades ago.[2] The BHVS petitioned repeatedly at a national policy level for HVD to be the subject of a NICE evaluation.

This guidance is an acknowledgement that patients living with HVD merited detailed consideration from NICE regarding their care. Also rising are the expectations of patients and, although medical practice is continuously improving, unless treatment is centred around best practice across the country (e.g. assessment within specialist heart valve clinics), those expectations may not be met.

The NICE process has taken three years and required a detailed and exhaustive review of the published clinical evidence and involved a consultation process that enabled significant feedback from BHVS and other stakeholders.

The Guidance

The NICE process is most effective in the assessment of randomised controlled trials (RCTs) and NICE committees normally avoid consensus statements. As an example, there is little evidence that providing information to patients is effective despite this being obviously sensible. However NICE have stepped outside their usual remit in calling for this. Thus, we wish NICE had gone further and made clearly beneficial recommendations for service delivery, such as:

- recommending that patients are seen in specialist heart valve clinics
- stipulating that patients should be cared for by a cardiologist who has competencies in valve disease
- recommending creation of Rapid Access Heart Valve Clinics – akin to rapid access chest pain clinics – for patients with suspected HVD and rapid onset of symptoms
- recommending the creation of heart valve centres of excellence

We made these points on behalf of patients during the stakeholder consultation process, but regrettably NICE replied that service delivery was outside the scope of this guidance's remit. BHVS will, however, continue to petition for these recommendations because they will save lives and benefit stakeholders in terms of better efficiency and better use of resources.

NICE has responded to some of the concerns that BHVS had over the draft document. The draft guidance stated that patients with a murmur and syncope (loss of consciousness) after exercise should be seen within 4 weeks. This was far too long, and the final document has been corrected to 2 weeks. We also recommended that patients with mild valve disease should not necessarily be discharged from follow-up and might, in some circumstances, warrant a repeat assessment after several years – this has also been incorporated into the final guidance.

Minimally invasive treatments

We welcome the recommendation from NICE to embrace minimally invasive cardiac surgery, where such services are available. For patients with severe aortic stenosis, NICE has sensibly balanced the surgical and transcatheter options in a fashion which, we believe, mirrors current UK practice. The NICE guidance states that transcatheter aortic valve implantation (TAVI) is an option for all patients with an unacceptably high risk of mortality or morbidity from surgery, patients who may have an unacceptably prolonged or strenuous recovery from surgery and also patients with low life-expectancy, either due to age or major co-morbidities. We believe this accurately reflects the discussions many clinicians have in daily practice and considers factors beyond surgical risk alone. Decision-making in patients with symptomatic severe aortic stenosis is often complex – BHVS supports decisions made by the heart team, taking into consideration not only surgical risk but also patient age, expectancy of life, frailty, as well as the co-existence of coronary artery disease and the risk for immediate or long term complications of TAVI determined by available access for the procedure, features of valve and aortic root morphology and severity and distribution of calcification of the valve.

Similarly, we welcome the guidance regarding keyhole treatments for the mitral valve, namely transcatheter edge-edge repair (TEER). The NICE guidance permits the use of TEER for patients with a severe leak across the mitral valve (mitral regurgitation) if they are unsuitable for surgery, whether they have 'primary' (organic) or 'secondary' (functional) regurgitation.

BHVS recognises the challenges of reconciling rapidly evolving evidence for invasive therapies in a patient group with complex care needs within a fiscally constrained environment. The BHVS would be keen to work with NICE to support clinically and cost effective, equitable HVD care in this era of innovation.

Summary

Guidelines are only of use if they are implemented and it is noteworthy that improvements in care between the first and second EuroHeart Valve Surveys[3-4] were minimal despite 7 intervening international guidelines. Far more important is to improve service delivery. Ultimately the Getting It Right First Time (GIRFT) report[5], the multi-Society document on multi-disciplinary meetings[6] and the BHVS service delivery recommendations or 'Blueprint'[7] will be far more useful than another set of guidelines.

How can we do better? We need to combine the benefits of our current processes. Guidelines produced by professional societies are comprehensive and mostly address real clinical problems but can be let down by vested interests and a relatively uncritical review of the literature. NICE has undisputed expertise in analysis of research studies, but the deliberate omission of issues related to service delivery (on grounds of being outside the scope of their guidance) inevitably produces a final document that is not geared to engineer the changes in healthcare provision that are required to improve quality and efficiency of care. These NICE guidelines are, however, a first step in the right direction.

For the next iteration, we call upon NICE to work in collaboration with professional societies like BHVS to try to improve care for real patients in the real world. BHVS will continue to strive to maintain its patient centered approach in our primary aim to 'educate, promote and inform' on all matters related to heart valve disease.

References

1. Heart valve disease presenting in adults: investigation and management. NICE Guideline NG208. https://www.nice.org.uk/guidance/NG208
2. National Service Framework: Coronary Heart Disease. First published March 2000. https://www.gov.uk/government/publications/quality-standards-for-coronary-heart-disease-care
3. Iung B *et al.* A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J* 2003; 1231-1243
4. Iung B et al. Contemporary Presentation and Management of Valvular Heart Disease. The EURObservational Research Programme Valvular Heart Disease II Survey. *Circulation* 2019; 140:1156-1169
5. Clarke S & Ray S. Cardiology – GIRFT Programme National Specialty Report. February 2021. https://www.gettingitrightfirsttime.co.uk/medical-specialties/cardiology/
6. Getting the best from the Heart Team: Guidance for the structure and function of cardiac multidisciplinary meetings. https://www.bhvs.org.uk/getting-the-best-from-the-heart-team-guidance-for-the-structure-and-function-of-cardiac-multidisciplinary-meetings/
7. Network Based Care for Heart Valve Disease – The BHVS Blueprint. https://www.bhvs.org.uk/bhvs-blueprint/

Summary of key new recommendations

Urgent Assessment

Urgent clinical assessment (within 2 weeks) is recommended for adult patients with a systolic murmur and exertional syncope (loss of consciousness)

Urgent clinical assessment (within 2 weeks) is recommended for adult patients with a murmur and severe symptoms (e.g. breathlessness with minimal effort, chest pain on exertion)

Valve Surveillance

Offer clinical review every 6-12 months for patients with severe valve disease not due for immediate referral for intervention

Consider echocardiography after 3-5 years in patients with mild aortic or mitral stenosis

Treatment

Aortic stenosis

Offer surgery (conventional or minimal access) to adults with severe aortic stenosis at low or intermediate surgical risk

Offer TAVI to adults with severe aortic stenosis at high or prohibitive surgical risk

Mitral regurgitation

Primary

Offer surgical valve repair to adults with severe primary MR that are suitable for surgery

Offer surgical valve replacement to adults with severe primary MR that are suitable for surgery, but the valve is unsuitable for repair

Offer transcatheter edge-edge repair (TEER) to adults with severe primary MR that are not suitable for surgery

Secondary

Consider surgical valve repair in patients with severe secondary MR that are undergoing surgery for a different reason (e.g. coronary artery bypass graft surgery) if the valve is suitable for repair

Consider surgical valve replacement in patients with severe secondary MR that are undergoing surgery for a different reason (e.g. coronary artery bypass graft surgery) if the valve is unsuitable for repair

Offer optimal medical therapy to patients with severe secondary MR

Consider transcatheter edge-edge repair (TEER) to adults with severe secondary MR that are not suitable for surgery and remain symptomatic despite optimal medical therapy