J.2 Symptomatic moderate heart valve disease

J.2.1 Research recommendation

What is the most clinically and cost-effective monitoring strategy (type and frequency of test) for adults with symptomatic moderate heart valve disease (aortic stenosis, aortic regurgitation, mitral stenosis, mitral regurgitation and tricuspid regurgitation) and no current indication for intervention?

J.2.2 Why this is important

Currently, it is not widely considered that moderate heart valve disease is able to cause symptoms, as the heart usually copes adequately with moderate valve disease. It is usually

only severe heart valve disease that can cause symptoms such as breathlessness, when the heart is no longer able to compensate for the degree of valve disease. However, some patients with moderate valve disease have symptoms such as breathlessness, and it is not known whether this is due to the valve disease or other conditions. It is also not known whether this group of patients progresses to severe disease more quickly than patients with moderate valve disease but without symptoms. Understanding more about this group of patients, and in particular what frequency and form of assessment and follow-up results in better outcomes, would be important for aiding clinical management decisions.

J.2.3 Rationale for research recommendation

Importance to 'patients' or the population	If we could determine the optimal frequency and type of follow-up, and whether this should differ from asymptomatic patients with moderate heart valve disease, these patients could avoid unnecessary investigations or treatments, or may require more frequent follow-up to identify any decompensation early and avoid irreversible cardiac damage.
Relevance to NICE guidance	No evidence was found on people with mild or moderate heart valve disease. Research would support recommendations to be made on the type and frequency of monitoring, and whether this should differ from asymptomatic patients with moderate heart valve disease.
Relevance to the NHS	Research in this area would inform NICE recommendations on the frequency and type of follow-up required for patients. If more frequent or a different type of follow-up was shown to reduce the number of people presenting with late decompensated heart failure, this could improve the long term outcome for patients, by avoid irreversible cardiac damage. If patients with moderate heart valve disease and symptoms were shown to be no different from patients with asymptomatic moderate heart valve disease, the two groups of patients could be managed similarly.
National priorities	None known
Current evidence base	No relevant studies were identified on people who are symptomatic and have moderate heart valve disease with no current need for intervention, including aortic stenosis, aortic regurgitation, mitral stenosis, mitral regurgitation and tricuspid regurgitation? Monitoring of this group is crucial to treatment because it enables identification of those patients for whom surgery is most timely, leading to improved survival and quality of life.
Equality considerations	None known

J.2.4 Modified PICO table

Population	Inclusion Adults aged 18 years and over who are symptomatic with moderate diagnosed heart valve disease and no current indication for intervention Severity assessed by echo and rated as per The British Society of Echocardiography Exclusion • Children aged less than 18 years. • Adults with congenital heart disease (excluding bicuspid aortic valves). • Tricuspid stenosis and pulmonary valve disease. • People who have had prior heart valve repair or replacement (transcatheter or surgical).
Intervention	Any of the following assessment strategies used for monitoring purposes, followed by appropriate valve intervention, in the specified population: Biomarkers (alone or in combination with echo): • BNP (B-type natriuretic peptide) • NT-proBNP (N-terminal prohormone brain natriuretic peptide) Imaging: • Echocardiography • CT (alone or in combination with echo) • CMR (cardiovascular magnetic resonance; alone or in combination with echo) Patient reported outcome measures (PROMS; alone or in combination with echo), including: • EuroQol • Minnesota Living With Heart Failure Questionnaire (MLHFQ) • Veterans Specific Activity Questionnaire Other methods: • Electrocardiogram (ECG) (alone or in combination with echo) • Clinical review only (no specific tests performed, as defined by the study authors) • Exercise testing (for example Bruce protocol; alone or in combination with echo)
Comparator	Other active comparator listed above No monitoring (for example, tests only performed if new symptoms emerge/symptoms worsen)

Outcome	Primary outcomes All-cause mortality; Cardiac mortality; Health-related quality of life (any validated measure) and Hospitalisation for heart failure or other cardiac reason (e.g., for syncope in severe AS) Secondary outcomes New-onset atrial fibrillation
Study design	Adequately powered randomised controlled trial (ideally)
Timeframe	Long term
Additional information	None