F.3 Severe heart valve disease

Table 9: Clinical evidence profile: Guideline adherent [clinical review + echocardiography every 12 (±6) months] vs. guideline non-adherent group

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Guideline adherent group	guideline non-adherent group	Relative (95% CI)	Absolute		
All-cause mortality - HR (adjusted) 1 year (follow-up median 4.5 years)												
1	observational studies	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	2/202 (0.99%)	2/98 (2%)	HR 0.65 (0.44 to 0.96)[4]	7 fewer per 1000 (from 1 fewer to 11 fewer)[5]	⊕OOO VERY LOW	CRITICAL

Cardiac mortality												
0	No evidence available											CRITICAL
Health-related quality of life (any validated measure)												
0	No evidence available											CRITICAL
Heart failure hospitalisation - HR (not adjusted) 6 months (follow-up median 4.5 years)												
1	observational studies	very serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	9/202 (4.5%)	15/98 (15.3%)	HR 0.6 (0.46 to 0.79)[6]	58 fewer per 1000 (from 30 fewer to 79 fewer)[7]	⊕OOO VERY LOW	CRITICAL
New-onset atrial fibrillation												
0	No evidence available											IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment as the interventions and comparisons in this study were indirect compared with the protocol - monitoring in the guideline adherent group may not have been 12 months in all patients and monitoring in the guideline nonadherent group was not defined and could have included various different strategies. There was also no information about aortopathy in the study, one of the confounders listed in the protocol.
[3] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
[4] The values reported in the paper (HR 1.54, 95% CI 1.04 to 2.29) were inverted in order to obtain the HR for the guideline adherent group vs. the non-adherent group to achieve the comparison of interest in the protocol
[5] Control group risk at 1 year from survival curve used. A larger benefit (100 fewer per 1000) was observed when the control group risk at 4 years was used; however, this was not included in the report as the 1-year time-point was closest to the time-point of 6 months specified in the protocol

[6] The values reported in the paper (HR 1.66, 95% CI 1.27 to 2.18) were inverted in order to obtain the HR for the guideline adherent group vs. the non-adherent group to achieve the comparison of interest in the protocol
[7] Control group risk at 6 months from survival curve used, A larger benefit (185 fewer per 1000) was observed when the control group risk at 4 years was used; however, this was not included in the report as the 1-year time-point was closest to the time-point of 6 months specified in the protocol