

## F.1 Surgical valve replacement

Table 14: Clinical evidence profile: DOAC versus VKA in surgical valve replacement

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	DOAC	VKA	Relative (95% CI)	Absolute		
<b>All-cause mortality at ≤12 months (follow-up mean 3 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>1</sup>	none	0/15 (0%)	8.3%	Peto OR 0.11 (0 to 5.44)	8 fewer per 1000 (from 28 fewer to 11 more) <sup>2</sup>	⊕⊕○○ LOW	CRITICAL
<b>Health-related quality of life at ≤12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Major bleeding at ≤12 months (follow-up mean 3 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>1</sup>	none	1/15 (6.7%)	8.3%	Peto OR 0.79 (0.05 to 13.6)	16 fewer per 1000 (from 78 fewer to 469 more)	⊕⊕○○ LOW	CRITICAL
<b>Minor bleeding at ≤12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Arterial thromboembolic events at ≤12 months (follow-up mean 3 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>1</sup>	none	1/15 (6.7%)	8.3%	Peto OR 0.79 (0.05 to 13.6)	16 fewer per 1000 (from 78 fewer to 469 more)	⊕⊕○○ LOW	CRITICAL
<b>Hospital re-admission at 12 months (follow-up mean 3 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>1</sup>	none	1/15 (6.7%)	8.3%	Peto OR 0.79 (0.05 to 13.6)	16 fewer per 1000 (from 78 fewer to 469 more)	⊕⊕○○ LOW	IMPORTANT
<b>Thrombus on imaging at ≤12 months (follow-up mean 3 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>1</sup>	none	0/15 (0%)	8.3%	Peto OR 0.11 (0 to 5.44)	8 fewer per 1000 (from 28 fewer to 11 more) <sup>2</sup>	⊕⊕○○ LOW	IMPORTANT
<b>All-cause mortality at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Health-related quality of life at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL

<b>Major bleeding at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-	-	CRITICAL
<b>Minor bleeding at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-	-	CRITICAL
<b>Arterial thromboembolic events at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-	-	CRITICAL

<sup>1</sup> Downgraded by 2 increments as the confidence interval crossed two MIDs

<sup>2</sup> Absolute effect calculated manually using risk difference as zero events in one arm of the study

**Table 15: Clinical evidence profile: VKA versus SAPT in surgical valve replacement**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	VKA	SAPT	Relative (95% CI)	Absolute		
<b>All-cause mortality at ≤12 months (follow-up 3-6 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>3</sup>	none	10/201 (5%)	4.7%	RR 1.22 (0.49 to 3.04)	10 more per 1000 (from 24 fewer to 96 more)	⊕○○○ VERY LOW	CRITICAL
<b>Health-related quality of life at ≤12 months - not reported</b>												
0	-	-	-	-	-	none	-	-	-	-	-	CRITICAL
<b>Major bleeding at ≤12 months (follow-up 3-6 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>4</sup>	none	12/201 (6%)	2.4%	RR 2.94 (0.97 to 8.95)	47 more per 1000 (from 1 fewer to 191 more)	⊕○○○ VERY LOW	CRITICAL
<b>Minor bleeding at ≤12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-	-	CRITICAL
<b>Arterial thromboembolic events at ≤12 months (follow-up 3-6 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>3</sup>	none	11/201 (5.5%)	6.3%	RR 0.82 (0.37 to 1.76)	11 fewer per 1000 (from 40 fewer to 48 more)	⊕○○○ VERY LOW	CRITICAL
<b>Hospital re-admission at 12 months (follow-up 6 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2</sup>	very serious <sup>3</sup>	none	25/167 (15%)	13%	RR 1.15 (0.67 to 1.97)	19 more per 1000 (from 43 fewer to 126 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Thrombus on imaging at ≤12 months (follow-up mean 6 months)</b>												

1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2</sup>	very serious <sup>3</sup>	none	0/167 (0%)	0.6%	Peto OR 0.13 (0 to 6.58)	10 fewer per 1000 (from 20 fewer to 10 more) <sup>5</sup>	⊕○○○ VERY LOW	IMPORTANT
<b>All-cause mortality at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Health-related quality of life at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Major bleeding at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Minor bleeding at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Arterial thromboembolic events at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL

<sup>1</sup> Downgraded by 1 increment as the majority of the evidence was at high risk of bias

<sup>2</sup> Downgraded by 1 increment as one study included people who had a CABG while having the valve replacement surgery. The people in the intervention arm were subsequently given warfarin and aspirin, instead of just warfarin.

<sup>3</sup> Downgraded by 2 increments as the confidence interval crossed both MIDs

<sup>4</sup> Downgraded by 1 increment as the confidence interval crossed one MID

<sup>5</sup> Absolute effect calculated manually using risk difference as zero events in one arm of the study

**Table 16: Clinical evidence profile: VKA and SAPT versus VKA alone in surgical valve replacement**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	VKA and SAPT	VKA	Relative (95% CI)	Absolute		
<b>All-cause mortality at ≤12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Health-related quality of life at ≤12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Major bleeding at ≤12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Minor bleeding at ≤12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Major systemic embolism or death from vascular causes at ≤12 months</b>												

1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1</sup>	very serious <sup>2</sup>	none	2/45 (4.4%)	9.1%	RR 0.49 (0.09 to 2.53)	46 fewer per 1000 (from 83 fewer to 139 more)	⊕○○○ VERY LOW	CRITICAL
<b>All-cause mortality at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Health-related quality of life at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Major bleeding at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Minor bleeding at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
<b>Arterial thromboembolic events at &gt;12 months - not measured</b>												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL

<sup>1</sup> Downgraded by 1 increment as the evidence reported thromboembolic events/vascular mortality and did not report thromboembolic events excluding mortality

<sup>2</sup> Downgraded by 2 increments as the confidence interval crossed both MIDs