F.1 Surgical valve replacement

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

	Quality assessment								Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	DOAC	VKA	Relative (95% Cl)	Absolute		
All-cause mortality at ≤12 months (follow-up mean 3 months)												
	randomised trials	risk of bias	inconsistency	no serious indirectness	very serious¹	none	0/15 (0%)	8.3%	Peto OR 0.11 (0 to 5.44)	8 fewer per 1000 (from 28 fewer to 11 more) ²	⊕⊕OO LOW	CRITICAL
Health-rela	ated quality of	r life at ≤12 mc	onths - not measure	ed in the second se	Т	r	1	1			T	ODITION
0	<u> -</u>	-	<u> -</u>	<u> </u>	<u>F</u>	none	-	-	-	-	L	CRITICAL
1		no serious) no serious indirectness	very serious ¹	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)	⊕⊕OO LOW	CRITICAL
Minor blee	ding at ≤12 m	onths - not m	easured				•				•	
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Arterial the	romboembolio	c events at ≤12	2 months (follow-u	p mean 3 months	s)		•				•	
	randomised trials			no serious indirectness	very serious¹	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)	⊕⊕OO LOW	CRITICAL
Hospital re	e-admission a	t 12 months (f	ollow-up mean 3 m	ionths)								
-	randomised trials			no serious indirectness	very serious¹	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)	⊕⊕OO LOW	IMPORTANT
Thrombus	on imaging a	t ≤12 months	(follow-up mean 3	months)								
-	randomised trials	no serious risk of bias		no serious indirectness	very serious¹	none	0/15 (0%)	8.3%	Peto OR 0.11 (0 to 5.44)	8 fewer per 1000 (from 28 fewer to 11 more) ²	⊕⊕OO LOW	IMPORTANT
All-cause i	mortality at >1	2 months - no	ot measured									
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Health-rela	ated quality of	life at >12 mc	onths - not measure	ed								
0	-	-	-	-	-	none	-	-	-	-		CRITICAL

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Major bleeding at >12 months - not measured												
0	-	-	-	-	-	none	-	1	-	-		CRITICAL
Minor ble	Minor bleeding at >12 months - not measured											
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Arterial th	Arterial thromboembolic events at >12 months - not measured											
0	-	-	-	-	-	none	-	-	-	-		CRITICAL

¹ Downgraded by 2 increments as the confidence interval crossed two MIDs ² 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 assessm	ent				of ents		Effect	Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	VKA	SAPT	Relative (95% Cl)	Absolute		
All-cause	mortality at ≤1	2 months (follo	w-up 3-6 months)		•							
2	randomised trials		no serious inconsistency	serious ²	very serious ³	none	10/201 (5%)	4.7%	RR 1.22 (0.49 to 3.04)	10 more per 1000 (from 24 fewer to 96 more)	⊕000 VERY LOW	CRITICAL
Health-rela	lealth-related quality of life at ≤12 months - not reported											
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Major blee	ding at ≤12 mo	onths (follow-u	p 3-6 months)									
2	randomised trials		no serious inconsistency	serious ²	serious ⁴	none	12/201 (6%)	2.4%	RR 2.94 (0.97 to 8.95)	47 more per 1000 (from 1 fewer to 191 more)	⊕000 VERY LOW	CRITICAL
Minor blee	ding at ≤12 m	onths - not me	asured									
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Arterial the	romboembolic	events at ≤12	months (follow-up	3-6 months)								
2	randomised trials		no serious inconsistency	serious ²	very serious ³	none	11/201 (5.5%)		RR 0.82 (0.37 to 1.76)	11 fewer per 1000 (from 40 fewer to 48 more)	⊕OOO VERY LOW	CRITICAL
Hospital re	-admission at	12 months (fo	llow-up 6 months)									
1		no serious risk of bias	no serious inconsistency	serious ²	very serious ³	none	25/167 (15%)	13%	RR 1.15 (0.67 to 1.97)	19 more per 1000 (from 43 fewer to 126 more)	⊕OOO VERY LOW	IMPORTANT
Thrombus	on imaging at	: ≤12 months (f	ollow-up mean 6 m	onths)								

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1		no serious risk of bias	no serious inconsistency		very serious ³	none	0/167 (0%)	0.6%	Peto OR 0.13 (0 to 6.58)	10 fewer per 1000 (from 20 fewer to 10 more) ⁵	⊕000 VERY LOW	IMPORTANT	
All-cause	All-cause mortality at >12 months - not measured												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL	
Health-rela	Health-related quality of life at >12 months - not measured												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL	
Major blee	ding at >12 m	onths - not mea	asured										
0	-	-	-	-	-	none	-	-	-	-		CRITICAL	
Minor blee	eding at >12 m	onths - not mea	asured										
0	-	-	-	-	-	none	-	-	-	-		CRITICAL	
Arterial th	Arterial thromboembolic events at >12 months - not measured												
0	-	-	-	-	-	none	-	-	-	-		CRITICAL	

¹ Downgraded by 1 increment as the majority of the evidence was at high risk of bias ² 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.

³ Downgraded by 2 increments as the confidence interval crossed both MIDs
⁴ Downgraded by 1 increment as the confidence interval crossed one MID
⁵ 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 assessm	ent	No of patients			Quality	Importance					
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	VKA and SAPT	VKA	Relative (95% CI)	Absolute				
All-cause i	All-cause mortality at ≤12 months - not measured													
0	-	-	-	-	-	none	-	-	-	-		CRITICAL		
Health-rela	ted quality of	life at ≤12 mor	oths - not measured	d										
0	-	-	-	-	-	none	-	-	-	-		CRITICAL		
Major blee	ding at ≤12 m	onths - not me	asured											
0	-	-	-	-	-	none	-	-	-	-		CRITICAL		
Minor blee	Minor bleeding at ≤12 months - not measured													
0	-	-	-	-	-	none	-	-	-	-		CRITICAL		
Major syst	emic embolis	n or death from	ajor systemic embolism or death from vascular causes at ≤12 months											

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1		no serious risk of bias	no serious inconsistency		very serious²	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)	⊕000 VERY LOW	CRITICAL
All-cause i	All-cause mortality at >12 months - not measured											
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Health-rela	Health-related quality of life at >12 months - not measured											
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Major blee	ding at >12 m	onths - not me	asured									
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Minor blee	ding at >12 m	onths - not me	asured									
0	-	-	-	-	-	none	-	-	-	-		CRITICAL
Arterial the	Arterial thromboembolic events at >12 months - not measured											
0	-	-	-	-	-	none	-	-	-	-		CRITICAL

¹ Downgraded by 1 increment as the evidence reported thromboembolic events/vascular mortality and did not report thromboembolic events excluding mortality ² Downgraded by 2 increments as the confidence interval crossed both MIDs

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