

Attachment 6 - Grading of Recommendations, Assessment, Development and Evaluations

Table S 1 Grading of Recommendations, Assessment, Development and Evaluations (GRADE) table with explanations of ratings for individual domains

Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Large consistent effect	Dose response	Confounders only reducing size of effect	
Implantable cardiac devices										
Infections	Low: Observational studies.	Serious limitation – downgrade by one: Result based on studies of serious risk of bias concerns.	No serious limitations – no downgrade: Similar point estimates and overlapping confidence intervals. Results of meta-analysis Cochran’s Q test ($p > 0.10$) and Higgins’s I^2 (<40%) indicated low heterogeneity.	Serious limitation – downgrade by one: Some differences in eligibility (reused devices provided when new devices were unavailable, reused devices provided to patients with low life expectancy, reused devices given to patients who could not afford new devices). Patients were older in the Linde <i>et al.</i> study compared with others. The gender breakdown varied	Serious limitation – downgrade by one: Reasonably narrow confidence intervals across all 4 studies (all with appreciable benefit and harm). One of 4 studies (Nava <i>et al.</i>) undertook a power calculation (and was adequately powered). Consequently, it was unclear whether other studies were	No serious limitation – no downgrade: Our search is comprehensive. Our findings were unadjusted.	No upgrade: Consistent findings, potential for confounders.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders.	Very low

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Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Large consistent effect	Dose response	Confounders only reducing size of effect	
				across studies ranging from 25% - 85% female. 3/4 studies did not report device brands.	adequately powered.					
Unexpected battery depletion	Low: Two observational studies.	No serious limitations – no downgrade: Result based on low risk of bias for all studies for this outcome.	No serious limitations – no downgrade: Similar point estimates and overlapping (relatively narrow) confidence intervals.	No serious limitations – no downgrade: Some differences in study population (eligibility, age, gender) and intervention (device brands and reprocessing location) unlikely to seriously influence this outcome.	Very serious limitation – downgrade by two: Wide confidence interval across 2 studies with events. One of 2 studies (Nava <i>et al.</i>) undertook a power calculation (and was adequately powered). Consequently, it was unclear whether other studies were adequately powered.	No serious limitations – no downgrade: Our search is comprehensive. Our findings were unadjusted.	No upgrade: Inconsistent findings.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders.	Very low

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Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Large consistent effect	Dose response	Confounders only reducing size of effect	

Cardiac catheters/cannulas

Major complications	Low: Three of four studies are observational.	Serious limitation – downgrade by one: Result based on serious concerns with respect to risk of bias in three of four studies in relation to this outcome.	No serious limitations – no downgrade:	Serious limitation – downgrade by one: Some differences in procedures (coronary angioplasty vs elective atrial fibrillation ablation). Three of four studies didn't report device brands. Devices were reprocessed externally in three of four studies.	Very serious limitation – downgrade by two: Wide confidence interval across studies with events. One study (Unverdorben <i>et al.</i>) undertook a power calculation (and was underpowered for procedure success). Other studies were likely adequately powered but did not undertake a power calculation.	No serious limitations – no downgrade: Our search is comprehensive. Our findings were unadjusted.	No upgrade: Inconsistent findings.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment for confounders	Very low
Total cost difference (per patient)	Low: Observational study	No serious limitation – no	Serious limitation – downgrade by one: One study.	No serious limitations – no downgrade:	Very serious limitation – downgrade by two:	No serious limitations – no downgrade:	No upgrade: One study.	No upgrade: Dose-response not applicable.	No upgrade: No adjustment	Very low

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Outcome	A priori ranking	Downgrade for					Upgrade for			Final grade
		Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Large consistent effect	Dose response	Confounders only reducing size of effect	
		downgrade: Moderate risk of bias in two domains.		Comparable population for intervention and comparison	Not reported.	Our search is comprehensive. Our findings were unadjusted.			for confounders	

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