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Are perioperative statins beneficial for cardiac surgery?

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Abstract

The use of perioperative statins has been proposed as a measure to reduce morbidity and mortality in cardiac surgery. However, their clinical role is controversial. Searching in Epistemonikos database, which is maintained by screening multiple databases, we identified 36 systematic reviews comprising 92 primary studies addressing the question of this article, including 22 randomized trials. We extracted data, combined the evidence using meta-analysis and generated a summary of findings following the GRADE approach. We concluded perioperative statins probably do not decrease mortality in cardiac surgery and it is unclear if they have any benefit because the certainty of the evidence is very low.

Problem

Cardiac surgery leads to high morbidity and mortality due to multiple causes such as atrial fibrillation, myocardial infarction, acute renal failure and stroke. On the other hand, statins are a family of drugs that have shown a reduction in cardiovascular events, mainly due to their clinical effects on lipid profile. However, pleiotropic effects have been proposed, including an acute anti-inflammatory mechanism, whose real clinical impact is a matter of debate.

In this context, it has been suggested that the use of perioperative statins may reduce morbidity and mortality in cardiac surgery.

Methods

We used Epistemonikos database, which is maintained by screening multiple databases, to identify systematic reviews and their included primary studies. With this information, we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

Key messages
- Perioperative statins probably do not decrease mortality in cardiac surgery.
- It is unclear whether perioperative statins have any benefit because the certainty of the evidence regarding the risk of atrial fibrillation, acute myocardial infarction, and acute renal failure is very low.
- Although there is a large number of systematic reviews on this topic, all have significant limitations or are out-of-date.

About the body of evidence for this question

What is the evidence. See evidence matrix in Epistemonikos later	We found 36 systematic reviews reported in 38 references [1],[2],[3],[4],[5],[6],[7],[8],[9],[10],[11],[12],[13], [14],[15],[16],[17], [18],[19],[20],[21],[22],[23],[24],[25],[26],[27],[28],[29],[30],[31],[32], [33],[34],[35],[36],[37],[38] which included 92 primary studies relevant for the question of this article, reported in 98 references [39],[40],[41],[42], [43],[44],[45],[46],[47],[48],[49],[50],[51],[52],[53],[54],[55], [56],[57], [58],[59],[60],[61],[62],[63],[64],[65],[66],[67],[68],[69],[70],[71],[72], [73],[74],[75],[76],[77],[78],[79],[80],[81],[82],[83],[84],[85],[86],[87], [88],[89],[90],[91],[92],[93],[94],[95],[96],[97],[98],[99],[100],[101], [102],[103],[104],[105],[106], [107],[108],[109],[110],[111],[112],[113], [114],[115],[116],[117],[118],[119],[120],[121],[122],[123], [124],[125], [126],[127],[128],[129],[130],[131],[132],[133],[134],[135],[136],[137]. Among them, 22 randomized controlled trials which are reported in 28 references [42],[44],[45],[49],[50],[51],[56],[57],[58],[59],[60],[61], [62],[70],[78],[84],[93],[97],[107],[110],[111], [116],[117],[120], [121],[124],[125],[134]. This table and this summary in general are based on the latter.
What types of patients were included	The characteristics of the included patients were: Regarding type of surgery, 17 trials [45],[50],[51],[56],[57],[58],[59],[60], [78], [93],[97],[116],[117],[120],[121],[124],[134] included only coronary reperfusion surgery; four any type of cardiac surgery [70],[84],[107],[111]; and one any type of cardiac surgery except coronary surgeries [42]. Seven studies excluded emergency surgery [42],[59],[107],[111], [117], [121],[124] and one study [60] included 87% elective surgeries. From the remaining trials it was not possible to obtain data from the systematic reviews on this variable.
What types of interventions were included	Regarding type of statin, three trials [42],[60],[124] used simvastatin, 15 trials used atorvastatin [45],[50],[58],[59],[70],[78],[84],[97], [107],[111],[116],[117],[120],[121],[134], two trials used rosuvastatina [57],[93], one trial used fluvastatin [51] and one trial used pravastatin/pitavastatina [56]. The doses ranged from 20 to 80 mg per day depending on the type of statin. All trials compared with placebo or standard treatment, except two trials [84],[116] that compared against a lower dose of statins.
What types of outcomes were measured	Systematic reviews grouped the outcomes as follows: • Atrial fibrillation • Arrhythmias • Acute myocardial infarction • Stroke • Acute renal failure • Need for renal replacement therapy • Length of hospitalization • Intensive care unit time • Need for surgical reintervention • Cost • Infections

Summary of findings

The information about the effects of perioperative statins on cardiac surgery is based on 22 randomized trials involving 4,335 patients. Eight trials reported mortality (735 patients) [50],[59],[60],[78],[107],[116],[117],[124]; 12 trials reported atrial fibrillation (3,020 patients) [50],[56],[57],[59],[78],[93],[107],[116],[117],[120],[124],[134]; 11 trials reported acute myocardial infarction (1,064 patients) [50],[51],[59],[60],[70],[78],[93],[107],[116],[120],[134] and two reported acute renal failure (117 patients) [57],[60].

The summary of findings is as follows:

- Perioperative statins probably do not decrease mortality in cardiac surgery. The certainty of the evidence is moderate.
- It is unclear whether perioperative statins decrease the risk of atrial fibrillation in cardiac surgery, because the certainty of the evidence is very low.
- It is unclear whether perioperative statins decrease the risk of acute myocardial infarction in cardiac surgery, because the certainty of the evidence is very low.
- It is unclear whether perioperative statins decrease the risk of acute renal failure in cardiac surgery, because the certainty of the evidence is very low.

Perioperative statins for cardiac surgery

Patients Cardiac surgery
Intervention Perioperative statins
Comparison Placebo or no intervention

Outcomes	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	WITHOUT perioperative statin	**WITH perioperative statin**		
	Difference: patients per 1000			
Mortality	5 per 1000	5 per 1000	RR 0.98 (0.14 a 6.82)	⊕⊕⊕◯ Moderate[1,2]
	Difference: 0 patients per 1000 (Margin of error: 5 less to 32 more)			
Atrial fibrillation	255 per 1000	140 per 1000	RR 0.55 (0.40 a 0.75)	⊕◯◯◯ Very low[1,3]
	Difference: 115 patients less per 1000 (Margin de error: 64 less to 153 less)			
Acute myocardial infarction	28 per 1000	18 per 1000	RR 0.62 (0.26 a 1.48)	⊕◯◯◯ Very low[1,2]
	Difference: 10 patients less per 1000 (Margin of error: 21 less to 14 more)			
Acute renal failure	158 per 1000	88 per 1000	RR 0.56 (0.09 a 3.47)	⊕◯◯◯ Very low[1,2]
	Difference: 70 patients less per 1000 (Margin of error: 114 less to 390 more)			

RR= Risk ratio.
Margin of error = 95% confidence interval (CI).
GRADE: evidence grades of the GRADE Working Group (see later in this article).

* The risk **WITHOUT perioperative statins** is based on the risk in the control group of the trials. The risk **WITH perioperative statins** (and its margin of error) is calculated from relative effect (and its margin of error).

[1] The certainty of the evidence was downgraded in two levels because of the high risk of bias of included trials. For the outcome mortality, we did not downgrade the certainty of the evidence since the presence of bias would reinforce the conclusion of no effect.
[2] The certainty of the evidence was downgraded in two levels due to imprecision because of the very wide confidence interval
[3] The certainty of the evidence was downgraded in one level due to publication bias as suggested by the funnel plot.

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕
High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕◯
Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

⊕⊕◯◯
Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕◯◯◯
Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.
† Substantially different = a large enough difference that it might affect a decision.

Other considerations for decision-making

To whom this evidence does and does not apply

- The evidence presented in this summary applies to patients with cardiac surgery, both after coronary revascularization and valvuloplasty.
- This summary does not include endovascular cardiac surgery, or vascular surgeries, either open or endovascular.

About the outcomes included in this summary

- The outcomes mortality, atrial fibrillation, acute myocardial infarction and acute renal failure were chosen for this summary, since they are the critical outcomes for decision-making on the use of perioperative statins. This selection is based on the opinion of the authors of the summary, but in general coincide with the outcomes mentioned by the systematic reviews, and it is based on the more frequent complications after cardiac surgery.

Balance between benefits and risks, and certainty of the evidence

- It is an intervention that probably has no impact on mortality, and any benefit is uncertain.
- It is call for caution that the largest existing trial has shown an increased risk of acute renal failure.
- It is not possible to make an adequate balance between benefits and risks due to the existing uncertainty.

What would patients and their doctors think about this intervention

- Based on the existing evidence, most clinicians should lean against the use of statins in this context.
- However, because of the low rate of adverse effects and the lack of clear recommendations in this topic, it is likely that some clinicians who put more value on an untested benefit will continue to use them.

Resource considerations

- Statins are currently a low-cost and easy-to-administer drug, so this factor should not condition decision-making.

Differences between this summary and other sources

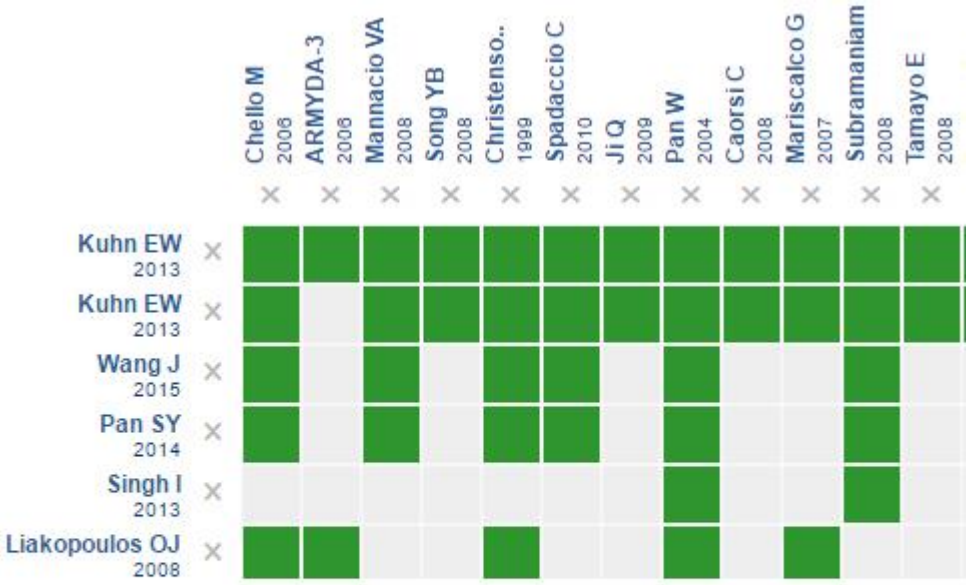
- Most of the systematic reviews identified favor the use of statins and attempt to support their conclusions with a different list of outcomes, not always with a clear pathophysiological background on the connection between statins and measured outcomes.
- It should be noted that the largest randomized trial [57] showed no effect on atrial fibrillation (the main outcome on which statin use would impact after cardiac surgery according to most investigators). It is also important to emphasize that only one systematic review [7] includes this trial. The negative results of this trial suggest that to a large extent, the benefits attributed to statins in cardiac surgery may be due to publication bias. The funnel plot strongly suggests there might be unpublished neutral/negative trials.
- The conclusions of this summary do not agree with the ACCF/AHA guideline for coronary artery bypass graft surgery [137], where routine use of statins in cardiac surgery is recommended.

Could this evidence change in the future?

- The likelihood that future research changes the conclusion of this summary is very high for some outcomes, due to the very low certainty of the existing evidence.
- There are at least eight ongoing studies (seven randomized trials [138],[139],[140],[141],[142],[143],[144] and one observational study [145]) according to the International Clinical Trials Registry Platform of the World Health Organization. These trials will help to clarify the actual clinical role of perioperative statins.
- Although there is an unusually high number of systematic reviews in this area, an up-to-date review is needed, that incorporates a rigorous analysis of the possible factors that might explain the discrepancies between the trials. There is an ongoing Cochrane review, which could play this role [146].

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.
The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.
The *rows* represent systematic reviews that share at least one primary study, and *columns* display the studies.
The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version:** Perioperative statins for cardiac surgery

Notes

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here http://dx.doi.org/10.5867/medwave.2014.06.5997.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database (www.epistemonikos.org).

These summaries follow a rigorous process of internal peer review.

Conflicts of interest
The authors do not have relevant interests to declare.

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