

Original Contribution

An assessment by the Statin Cognitive Safety Task Force: 2014 update

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Statins;
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Iatrogenesis

Abstract: The National Lipid Association's Safety Task Force convened a consensus conference of experts to develop a position statement on cognitive function to revise and update that published originally by the Association in the 2006 assessment of statin safety by a panel of neurologists. The current expert panel was charged with addressing the specific issue of potential adverse cognitive effects attributable to statins. Search strategies recently used in systematic reviews were used to identify relevant evidence using keywords and topics via Medline searches from 1966 to December 2013. Manual searches of bibliographies were also conducted. Panel members were asked to use the evidence to formulate answers to a series of questions of relevance to the subject matter. The strength of recommendations and quality of evidence were graded using accepted contemporary definitions and procedures. Recommendations to patients, health professionals, and researchers were put forth by the panel to aid in daily clinical decision making, and in future research endeavors.

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Evidence grading: Strength of recommendation*

Grade	Strength of recommendation
A	Strong recommendation There is high certainty based on the evidence that the net benefit** is substantial
B	Moderate recommendation There is moderate certainty based on the evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate
C	Weak recommendation There is at least moderate certainty based on the evidence that there is a small net benefit
D	Recommend against There is at least moderate certainty based on the evidence that it has no net benefit or that the risks/harms outweigh benefits
E	Expert opinion There is insufficient evidence or evidence is unclear or conflicting, but this is what the expert panel recommends
N	No recommendation for or against There is insufficient evidence or evidence is unclear or conflicting

*The system was adapted as a hybrid of the National Heart Lung and Blood Institutes (NHLBI) rating system (NHLBI cardiovascular-based methodology) used in the new American Heart Association/American College of Cardiology cholesterol guidelines¹ and adapted from the original Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of evidence rating.²

**Net benefit is defined as benefits minus risks/harms of the service/intervention.

Evidence grading: Quality of evidence

Type of evidence	Quality rating*
Well-designed, well executed RCTs that adequately represent populations to which the results are applied and directly assess effects on health outcomes Well-conducted meta-analyses of such studies Highly certain about the estimate of effect; further research is unlikely to change our confidence in the estimate of effect	High
RCTs with minor limitations affecting confidence in, or applicability of, the results Well-designed, well-executed nonrandomized controlled studies and well-designed, well-executed observational studies Well-conducted meta-analyses of such studies Moderately certain about the estimate of effect; further research may have an impact on our confidence in the estimate of effect and may change the estimate	Moderate
RCTs with major limitations Non-randomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results Uncontrolled clinical observations without an appropriate comparison group (eg, case series, case reports) Physiological studies in humans Meta-analyses of such studies Low certainty about the estimate of effect; further research is likely to have an impact on our confidence in the estimate of effect and is likely to change the estimate.	Low

RCT, randomized controlled trial.

This was the system used in the new American Heart Association/American College of Cardiology cholesterol guidelines¹ that were published in the 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report from the Panel members appointed to the Eighth Joint National Committee (JNC 8).³

Taken from James PA, Oparil S, Carter BL, et al. 2014 Evidence-based guideline for the management of high blood pressure in adults: Report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. 2013 Dec 18. doi: 10.1001/jama.2013.284427 [Epub ahead of print]. Permission to reuse table granted from the American Medical Association.

*The evidence quality rating system used in this guideline was developed by the National Heart, Lung, and Blood Institute's (NHLBI's) Evidence-Based Methodology Lead (with input from NHLBI staff, external methodology team, and guideline panels and work groups) for use by all the NHLBI cardiovascular disease guideline panels and work groups during this project. As a result, it includes the evidence quality rating for many types of studies, including studies that were not used in this guideline. Additional details regarding the evidence quality rating system are available in the online Supplement.

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