Error in USPSTF Report on Statin Use

The 2016 review1 for the US Preventive Services Task Force on statins for prevention of cardiovascular disease in adults had errors in the analysis of statins vs placebo and cardiovascular mortality. For the JUPITER trial, we interpreted “MI, stroke or cardiovascular death” as reported in the main trial publication2 as “myocardial death, stroke death, or cardiovascular death,” when it meant “nonfatal myocardial infarction, nonfatal stroke, or cardiovascular death.” Therefore, the analysis erroneously included nonfatal myocardial infarction and stroke events (83/8901 vs 157/8901 in the rosuvastatin vs placebo groups, respectively) in the analysis of cardiovascular mortality (Figure 3, panel B in the evidence review). The US Food and Drug Administration (FDA) review of atorvastatin reported 29 vs 37 cardiovascular mortality events in the rosuvastatin vs placebo groups, respectively, in JUPITER.3 However, a subsequent publication from 2 of the original JUPITER authors4 reported numbers of confirmed cardiovascular deaths of 35 vs 43 (not including 16 vs 25 cases of sudden death) in the rosuvastatin vs placebo groups. For the ASTRONOMER trial, data for cardiovascular deaths were transposed from another trial (2/103 vs 12/79 for statins vs placebo); the correct data are 2/134 vs 5/135.5

To correct these errors, we performed a revised meta-analysis for statins vs placebo and cardiovascular mortality using the FDA review data for JUPITER (29/8901 vs 37/8901 events) and the corrected data for ASTRONOMER (2/134 vs 5/135 events). Compared with our original JAMA publication, the pooled estimate for cardiovascular mortality was still statistically significant though attenuated (risk ratio [RR], 0.82 [95% CI, 0.71-0.94]); I² = 0% instead of RR, 0.69 [95% CI, 0.54-0.88]; I² = 54%) and the absolute risk difference was smaller (0.20% instead of 0.43%). Results were similar when the cardiovascular mortality data reported in the 2010 JUPITER publication were used for the meta-analysis or when sudden deaths reported in the 2010 JUPITER publication were included as cardiovascular deaths.

Data used in the other meta-analyses in the review were reviewed and indicated only minor rounding differences that had no effect on pooled estimates for statins vs placebo and all-cause mortality (RR, 0.86 [95% CI, 0.80-0.93]; absolute risk difference [ARD], 0.40%), fatal plus nonfatal myocardial infarction (RR, 0.64 [95% CI, 0.57-0.71]; ARD, 0.81%), fatal plus nonfatal stroke (RR, 0.71 [95% CI, 0.62-0.82]; ARD, 0.38%), and composite cardiovascular outcomes (RR, 0.70 [95% CI, 0.63-0.78]; ARD, -1.39%). We sincerely regret the error.

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Conflict of Interest Disclosures: Dr Chou reported receiving advisory board fees from Ferring and Pfizer. Dr Chou and co-authors who contributed to this study have no other financial disclosures.


CORRECTION

Incorrect Data in Text: In the US Preventive Services Task Force (USPSTF) Recommendation Statement entitled “Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation Statement,” published in the November 15, 2016, issue of JAMA, incorrect data were reported in the text. In the first paragraph of the “Statin Use in Adults Aged 40 to 75 Years” subsection and in the third paragraph of the “Benefits of Statin Use” subsection, the text “RR, 0.69 [95% CI, 0.54-0.88];” should have read “RR, 0.82 [95% CI, 0.71-0.94].” The certainty, magnitude of net benefit, and grades of the USPSTF recommendation remain the same. This article was corrected online.


Incorrect Data in Text, Table, Figure, and Supplement: In the US Preventive Services Task Force Evidence Report entitled “Statins for Prevention of Cardiovascular Disease in Adults: Evidence Report and Systematic Review for the US Preventive Services Task Force,” published in the November 15, 2016, issue of JAMA,1 incorrect data were reported. In the abstract Results, the data reported for cardiovascular mortality should have read “RR, 0.82 [95% CI, 0.71 to 0.94]; I² = 0%; ARD, -0.20% [95% CI, -0.35% to -0.05%]; I² = 11%.” In the second paragraph of the “Benefits of Statin Treatment” subsection in the text, the data reported for cardiovascular mortality should have read “RR, 0.82 [95% CI, 0.71 to 0.94]; I² = 0%; ARD, -0.20% [95% CI, -0.35% to -0.05%]; I² = 11%.” Two paragraphs later, the sentence “For cardiovascular mortality, statistical heterogeneity was present (I² = 54%),” but the estimate was similar using the profile likelihood method (RR, 0.71 [95% CI, 0.55 to 0.88]); should have been deleted, and the text 2 paragraphs later should have...
Funnel plot asymmetry was not observed for outcomes reported in at least 10 trials, except for cardiovascular mortality (P = .049 for Egger test). In the first paragraph of the Discussion, the data reported for cardiovascular mortality should have read “RR, 0.82 after 2-6 years [95% CI, 0.71 to 0.94]; I² = 0%; ARD, −0.20%; [95% CI, −0.35% to −0.05%]; and the NNT for cardiovascular death should have been reported as 500. In Table 3, “Key Question 1a” section, “Summary of Findings” column, the data reported for cardiovascular mortality should have read “RR, 0.82 [95% CI, 0.71-0.94]; I² = 0%; ARD, −0.20%; NNT, 500.”Incorrect data also appeared in Figure 3 and the online supplement. This article was corrected online.


Incorrect Data in Text: In the Editorial entitled “Statins for Primary Prevention: The Debate Is Intense, But the Data Are Weak” published in the November 15, 2016, issue of JAMA,1 incorrect data were reported in the text. In the first sentence of the second paragraph on the first page, the absolute benefit for use of statins should have been reported as 0.20%, rather than 0.43%, for cardiovascular mortality. This article was corrected online.


Incorrect Percent Values Reported in Text and Table 1: In the Research Letter entitled “Change in Prevalence of Disabilities and Accommodation Practices Among US Medical Schools, 2016 vs 2019” published in the November 26, 2019, issue of JAMA,1 incorrect percent values were reported in the text and in Table 1. A sentence in the Results should have read: “Of the 64 schools that responded in both years, the total number of students reporting disabilities increased from 1142 (2.9%) in 2016 to 2028 (4.9%) in 2019 (difference, 1.9% [95% CI, 1.8%-2.3%]; relative increase, 69%)(Table 1).” In Table 1, the overall percent of students with disability in 2016 should have been reported as 2.9%, and in 2019, the overall percent should have been reported as 4.9%. Correction of these values does not affect the results, which remain as a 69% relative increase. This article was corrected online.


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