Industry-Funded CV Trials: Biased to Positives?

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Contributing Writer

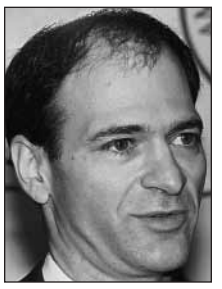
Clinical trials in the field of cardiovascular medicine that are funded by for-profit groups like drug companies and device manufacturers are more likely to report positive findings than are those funded by not-for-profit groups.

The research community discovered that this was true of clinical trials published between 1990 and 2000, and it instituted some changes to address the issue. To determine whether more recent clinical trials are still affected by this apparent bias, two investigators surveyed the reported outcomes of 349 consecutive cardiovascular randomized clinical trials published in 2000-2005 in the Journal of the American Medical Association, The Lancet, and the New England Journal of Medicine.

"By focusing on manuscripts published in these three journals, we were able to limit our analysis to trials considered to be of high quality on the basis of prior rigorous peer and editorial review," explained Dr. Paul M. Ridker and Jose Torres of Harvard Medical School, Boston.

A total of 109 (31%) of these trials were financed exclusively by not-for-profit groups such as the federal government, state governments, or foundations. Another 153 (44%) were financed exclusively by for-profit groups such as drug or device manufacturers. And 66 (19%) were funded jointly by both types of organizations. No source of funding was noted for the remaining 21 trials (6%).

Among the not-for-profit trials, approximately half found that newer treatments were no better than or not as good as the standard of care. In contrast, more than 67% of the for-profit trials found that newer treatments were superior to the standard of care, the investigators said (JAMA 2006;295:2270-4).



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DR. RIDKER

The proportion of jointly funded trials that favored new treatments was midway between these two points, at 56%.

A similar pattern was observed for the subset of 202 randomized clinical trials that evaluated cardiovascular drugs. The proportions that favored newer pharmaceuticals over the standard of care were 39% of the not-for-profit trials, 54% of the jointly funded trials, and 65% of the for-profit trials.

For the 38 trials that assessed cardiovascular devices, half of the not-for-profit trials favored new devices over the standard of care, compared with 69% of the jointly funded trials and 82% of the for-profit trials.

"These contemporary data appear to show that incentives surrounding for-profit organizations have the potential to influence clinical trial outcomes," Dr. Ridker and Mr. Torres noted.

In addition, the researchers found there was "minimal" evidence of publication bias. "Contrary to the often-voiced concern that major journals do not report null studies, we found that a substantial proportion of the cardiovascular trials published in JAMA, The Lancet, and the New England Journal of Medicine between 2000 and 2005 reported either no significant differences between therapies (34.6%) or a significant difference favoring the standard of care over newer treatments (6.8%)," they said. ■