

Study suggests probable scientific misconduct in bone health studies

November 9 2016

A new study suggests probable scientific misconduct in at least some of 33 bone health trials published in various medical journals. The study used statistical methods to detect scientific misconduct or research fraud and calls into question the validity of a body of research work led mainly by one researcher in Japan. The study is published in the November 9, 2016, online issue of *Neurology*, the medical journal of the American Academy of Neurology.

"Our use of [statistical methods](#) to examine the integrity of the data in 33 randomized controlled [trials](#) raises serious concerns about the reported results in those trials," said study author Mark J. Bolland, MBChB, PhD, of the University of Auckland in New Zealand.

Bolland and his team analyzed the 33 studies, three of which were published in *Neurology* and retracted this summer after the author, Yoshihiro Sato, MD, of Mitate Hospital in Tagawa, Japan, admitted to scientific misconduct. Sato accepted full responsibility, admitting fabrication of the fraudulent *Neurology* papers, which reported on the effects of therapies to reduce hip fractures both after stroke and in Parkinson's disease patients. Sato stated that none of the coauthors participated in any misconduct and were named as authors on an honorary basis only. Sato requested retraction of the three studies.

For the analysis of the 33 trials, 26 of which Sato was lead author, Bolland's team conducted a rigorous review and found reported results that differed markedly from what could be expected statistically; further,

the results were remarkably positive.

The characteristics of the groups of people chosen to participate in the trials were much more similar than would have happened by chance. The trials reported large reductions in hip fractures, no matter what treatment was used, that were much greater than those reported in similar trials from other research groups. Overall in the 33 trials, the people receiving the therapy were 78 percent less likely to break a hip than the control group, while several meta-analyses of other trials found either no benefit of the treatments or a benefit of less than 40 percent.

Bolland's team also found multiple examples of inconsistencies between and within trials, errors in reported data, misleading text, duplicated data and text as well as uncertainties about ethical oversight.

"The researchers were remarkably productive, conducting 33 [randomized controlled trials](#) within 15 years, the outcomes of each being remarkably positive," said Bolland. "Our analysis suggests that the results of at least some of these trials are not reliable. In addition, results from these trials were not consistent with results found in similar studies by other researchers."

"This statistical analysis demonstrates probable [scientific misconduct](#) on a large scale," said Robert A. Gross, MD, PhD, of Rochester, N.Y., Editor-in-Chief of *Neurology* and Fellow of the American Academy of Neurology, who wrote a corresponding editorial. "Fraud in an individual paper may be difficult to detect. One cannot conclude that any one study in the analysis is, or is not, fraudulent. As part of our due process, we have notified other editors of journals that published papers by Sato and colleagues, communicated with Sato's institution, and published retractions of the three papers and a letter published in *Neurology*."

Provided by American Academy of Neurology

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