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ORIGINAL ARTICLE

Funding sources and financial disclosures, and their relationship to study outcomes and level of evidence in the *Journal of Shoulder and Elbow Surgery*

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Hypothesis/Background: Concern exists regarding the reliability of published manuscripts due to influence of industry funding and author financial conflicts of interest (COI). We aim to determine whether COI affect the outcome of a research study or the level of evidence (LOE).

Methods: We reviewed 244 consecutive original articles in *Journal of Shoulder and Elbow Surgery* from January 2014 to December 2014. Articles included only those available in the printed journal. For LOE, 178 articles from the Shoulder and Elbow section were used (basic science articles were excluded). COI was determined by comparing financial disclosures and stated funding sources to the study content.

Results: COI were present in 44 of 244 articles (18%); of these, 24 (55%) had positive outcomes. Of the 200 without COI, 128 (64%) had positive outcomes. This difference in proportions was determined to be significant ($P = .007$). COI were present in 27 shoulder and elbow articles; of these, only 1 was LOE I or II (4%). Of the 151 without COI, 34 (23%) were LOE I or II. This difference in proportions was determined to be significant ($P = .023$).

Conclusion: We found that *Journal of Shoulder and Elbow Surgery* articles with COI are neither more likely to have positive outcomes nor higher LOE than those with no COI. Although the χ^2 analysis found a statistically significant relationship between COI and study outcomes, the study outcomes were more often positive in articles without COI. This is contrary to previously published analyses that found outcomes to be more positive in articles with COI.

Level of evidence: Survey Study; Literature Review

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During the past 30 years, the prevalence of industry funding for orthopedic research and the number of disclosed conflicts of interest (COI) have increased significantly.¹³ The relationship between orthopedic research/researchers and

industry has been heavily scrutinized, even finding its way into an investigation by a United States Senate Finance Committee in 2012.⁷ Although the relationship has allowed for an increase in published articles and knowledge within orthopedics, many began to question what other effects these COI had.

In 2011, the *Journal of Shoulder and Elbow Surgery (JSES)* editor was one of 20 orthopedic journal editors who signed a consensus statement and agreed to adopt the International Committee of Medical Journal Editors form for full financial disclosure.² Rather than state simply whether COI exist, the policy provides readers with information about the type and nature of financial disclosure by the authors. This policy allows the reader to determine whether financial interests may have influenced the research, rather than the author, reviewers, and editors making that decision before publication; in fact, one of the goals stated by Fischgrund was the for use of the form to “lead to a fuller and clearer understanding of potential author COI on the part of our readers.”² With the new policy comes a responsibility to help readers better interpret the effects that the various sources of COIs have on orthopedic research.

Previous studies have looked specifically at industry funding or pharmaceutical influences. Friedman et al³ found that 16% to 33% of manuscripts published in *The New England Journal of Medicine* or *The Journal of the American Medical Association* had at least 1 author with COI. They determined that a strong association existed with these manuscripts and the study having a favorable outcome. Lexchin et al⁵ specifically looked at pharmaceutical influence on drug studies and determined that studies were more likely to have an outcome favorable to the funder. Lynch et al⁶ found that commercially funded studies were no more likely than unfunded studies to have positive outcomes but were more likely to be published. Noordin et al⁸ found that industry funding results in lower levels of evidence (LOE) in published research but did not analyze the effect that financial COI had on LOE. Although the body of knowledge is growing, gaps still exist in the study of the effect financial COI and funding sources have on the outcomes of published orthopedic research.

This study assessed study outcomes and LOE related to COI based on the stated sources of funding and financial disclosures. We were also interested in observing the spectrum of funding in relation to country of origin of the study, the clinical setting (academic vs. private), and whether the study dealt with a surgical procedure. We hypothesized (1) that there would be a higher proportion of studies with positive outcomes in the COI group compared with those that had no COI; (2) that there would be a higher proportion of studies with positive outcomes in the industry-funded group compared with those that received noncommercial funding or were unfunded; and (3) that the proportion of studies with COI would be lower in studies with LOE I or II compared with studies with LOE III, IV, or V.

Materials and methods

The print version of *JSES*, Volume 23, was the source for 244 consecutive articles for calendar year 2014 (January 2014–December 2014). The search excluded review articles or editorials and articles that appeared in the online journal only.

Categoric data were extracted from each article by a single member of the research team. The data collected included location (North America, Europe, or other), research setting (academic or private), LOE, study design, sample size, domain (surgical or non-surgical), funding source, type of funding (academic/university, foundation, government, industry, or none disclosed), number of authors with a financial disclosure, and type of financial disclosure (consulting, speaking fees, employment; education, research support; royalties, equity; or none disclosed).

To categorize sample size, we used the classification scheme outline by Okike et al¹⁰ in an outcomes analysis in the *Journal of Bone and Joint Surgery*. Articles with a sample size of 1 to 10 were classified as small, 11 to 100 as medium, and greater than 101 as large.

Baldwin et al¹ previously found that the average LOE for orthopedic research falls between Level II and III. As such, for statistical analysis we sorted articles into 2 groups by LOE: higher LOE (I or II) and lower LOE (III, IV, or none).

Because *JSES* only lists financial disclosures and funding sources without determining whether COI exist, a determination had to be made regarding COI. We elaborated on a definition in a previous study³ to determine whether COI existed; specifically, COI existed if (1) the source of funding was from a company with a compelling financial interest in the outcome of the work, (2) at least 1 of the authors had financial disclosures that were directly related to the subject of the work, or (3) at least 1 of the authors was the employee of a company with compelling financial interest in the subject of the work.

The final variable of interest was study outcomes. Manuscripts were placed into 1 of 4 categories—positive, negative, neutral, or other—according to a methodology adapted from Hasenboehler et al⁴ with adjustments based on a study by Noordin et al⁸; similar methods were used in a meta-analysis by Sando et al.¹² Two researchers sorted each manuscript independently, and any discrepancy between the reviewers was discussed, and a final determination was made.

In the first subset of manuscripts, a new technique was compared with the current standard of care or a surgical technique was compared with conservative, nonsurgical treatment. Outcomes were positive if the new/surgical technique compared favorably with the current standard of care/conservative treatment; negative if the new/surgical technique did not compare favorably to the current standard of care/conservative treatment or if there was no significant difference between the two; or neutral if the new/surgical technique compared favorably to the current standard of care/conservative treatment but with major caveats or significant adverse effects.

For all other articles, the study outcomes were based on the stated hypotheses. Outcomes were positive if most of the hypotheses were supported, negative if most of the hypotheses were not supported, or other if a clear, concise hypothesis was not stated.

From the data gathered, we performed χ^2 analyses of independence to determine whether a statistically significant relationship existed between categoric variables and the 3 variables of interest: study outcomes, LOE, and COI. The χ^2 analysis for LOE ex-

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