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Evaluation of Spin in the Abstracts of Otolaryngology Randomized Controlled Trials

Craig M. Cooper, BS; Harrison M. Gray, BS; Andrew E. Ross, BS; Tom A. Hamilton, DO; Jaye Bea Downs, DO; Cole Wayant, BS; Matt Vassar, PhD

**Objective:** Spin, the misrepresentation and distortion of research findings, has been shown to affect clinical decision making. Spin has been found in randomized controlled trials (RCTs) published in various fields of medicine, but no study has tested for the presence of spin in otolaryngology RCTs. The purpose of this study is to evaluate the abstracts of RCTs found in the otolaryngology literature for spin.

**Methods:** In this cross-sectional analysis, we analyzed the abstracts of RCTs for spin using a pilot-tested form. Double data extraction was performed by two blinded authors, and discrepancies were resolved using mutual discussion.

**Results:** Out of the 534 PubMed citations retrieved by our search string, 162 parallel-group RCTs with clearly defined primary and secondary endpoints were identified. Further analysis identified 47 trials with nonsignificant primary outcomes, which were then evaluated for spin. Spin was identified in 33 of the 47 (70%) abstracts. Spin was found in the results sections of 25 (53%) of the included abstracts and was found in the conclusion section of 27 (57%) of the abstracts. Spin was not present in the titles of any of the included studies.

**Conclusion:** Spin was common in our sample of otolaryngology RCTs. Spin may potentially create false impressions about the true validity of a drug or intervention. Further research needs to test for potential clinical implications of spin in the otolaryngology literature.

**Key Words:** Randomized controlled trials, spin, abstracts, evidence-based medicine.

**Level of Evidence:** NA

**INTRODUCTION**

Randomized-controlled trials (RCTs) play an important role in clinical decision making. These trials help shape clinical practice guidelines and are fundamental to evidence-based practice. The American Academy of Otolaryngology–Head and Neck Surgery Foundation considers RCTs as grade B or level 2 evidence, superseded only by a systematic review of RCTs. This ranking means that RCTs are an important study design for assessing both treatment and harm. For example, the newest clinical practice guideline on dysphonia uses RCTs to recommend against the use of corticosteroids prior to visualization of the larynx and against the routine prescription of antibiotics to treat dysphonia. The guideline also uses RCTs to recommend voice therapy for patients with dysphonia that is amenable to it. Given the central role of RCTs in evidence-based clinical practice, rigorous standards of reporting are necessary, beginning with the abstract.

Abstracts play an important role in clinical decision making and should portray findings of the study as accurately and succinctly as possible. RCT abstracts have been shown to directly influence reader opinions on treatments or interventions. Further, it has also been shown that practitioners may use abstracts alone to guide clinical decision making owing to factors such as paucity of time, limited access to full text, or the inability to critically evaluate a study. For example, a study in a tertiary care hospital found that more than a third of residents frequently used abstracts to answer clinical questions. Another study performed in the early 1990s indicated that two-thirds of residents frequently used abstracts to answer clinical questions. This misrepresentation and distortion of research findings is called spin. In 2010, Boutron et al. explored the presence of spin in RCTs that reported statistically nonsignificant primary...
endpoints. They found that trials with nonsignificant primary endpoints often emphasized clinical benefit with a significant subgroup analysis or secondary endpoint, thus demonstrating the presence of spin. To date, no studies have explored the role of spin in otolaryngology RCTs. In this study, we aim to assess the frequency and manifestations of spin in abstracts of otolaryngology clinical trials and assess whether funding source affected the rates of spin.

MATERIALS AND METHODS

This study was conducted in accordance with a previously written and publicly available protocol available via the Open Science Framework. Examples of the types of spin assessed in this study are provided in Supporting Table SI. We searched PubMed on April 24, 2018, for RCTs of otolaryngology treatments in humans. We used the following search strategy: ("0023-852X"[Journal] OR "1043-3074"[Journal]) OR "0194-5998"[Journal] OR "2168-6181"[Journal] AND (Clinical Trial[ptyp] AND ("2010/01/01"[PDAT] : "2017/12/31"[PDAT])), where each number is a journal ISSN. Journals were chosen from Google Scholar Metrics (Google Inc., Mountain View, CA) and priority was given to ranking as well as relevance to clinical otolaryngology. The following journals were included (in the order they appear in the search strategy): The Laryngoscope; Head and Neck; Otolaryngology—Head and Neck Surgery; and JAMA Otolaryngology—Head & Neck Surgery. Search results were added to a PubMed collection and exported to Rayyan for screening by title and abstract.

C.M.C. and H.M.G. screened records for inclusion and extracted data for spin. Prior to the start of screening for inclusion and data extraction, both authors underwent training. We drew heavily from the seminal publication on spin in randomized trials with nonsignificant endpoints to develop training material, define spin, and devise extraction forms. Training videos were created by C.W. to define spin and explain the screening and data extraction procedures. Each screener and extractor watched these videos and then underwent in-person training to ensure understanding and calibration between reviewers. All discrepancies were resolved via group discussion.

To be included, a trial had to randomize humans to an intervention, statistically compare two or more groups, and have a nonsignificant primary endpoint. Records were excluded if they did not meet these criteria. Data extraction was done using a pilot-tested Google Form (Google Inc.). Items extracted from each included trial were the title, journal, funding source, comparator arm, primary endpoint, statistical analysis of the primary endpoint, secondary endpoints, statistical analysis of secondary endpoints, and trial registration number (if reported). Extractors were then asked whether spin was present in the abstract of the randomized trial. Spin in the title, abstract results, abstract conclusions, and selection of reported endpoints were considered.

We used the Boutron et al. definition of spin in randomized trials with nonsignificant primary endpoints; specifically, spin is the “use of specific reporting strategies, from whatever motive, to highlight that the experimental treatment is beneficial, despite a statistically nonsignificant difference for the primary outcome, or to distract the reader from statistically nonsignificant results (pg. 2058).”

We considered spin to be present if trial authors focused on statistically significant results, interpreted statistically nonsignificant results as equivalent or noninferior; used favorable rhetoric in the interpretation of nonsignificant results (e.g., “trend toward significance”), or claimed benefit of an intervention despite statistically nonsignificant results. If authors focused on statistically significant results, we catalogued whether they were associated with a within-group comparison, subgroup analysis, statistically significant secondary endpoint, or modified treatment population. All other strategies of spin that were apparent but did not fall under one of the above categories were recorded as authors extracted data.

Summary statistics (frequencies and proportions) were calculated using Google Sheets (Google Inc.). Odds ratios were calculated using Stata 13.1 (StataCorp, LLC, College Station, TX).

RESULTS

General Characteristics

Of the 534 PubMed citations retrieved by our search string, 162 parallel-group RCTs with clearly defined...
primary and secondary endpoints were identified (Fig. 1). The characteristics of these included studies can be seen in Figure 1. Most of the studies evaluated a pharmacological or surgical intervention against active treatments (31 of 47, 66%), and 14 (14 of 47, 29%) compared against a placebo or sham procedure. The source of funding for 11 (11 of 47, 23%) of the trials was industry, whereas nearly half (23 of 47, 48%) did not mention a source of funding. Trial registration numbers were reported in 20 (20 of 47, 42%) of the included studies. The primary outcome was clearly stated in either the results or methods section of 28 (28 of 47, 59%) of the included abstracts. We found that 20 (20 of 47, 42%) of the included abstracts had no reported numerical value of significance for the primary outcome, although further analysis of those 20 abstracts revealed that 16 (16 of 20, 80%) described a nonsignificant finding regarding the primary outcome.

**Primary Endpoint**

Spin was identified in 33 of the 47 (33 of 47, 70%) abstracts. Spin was not present in the titles of any of the included studies.

**Spin in Results.** Spin was found in the results sections of 25 (25 of 47, 53%) of the included abstracts. The most common strategy employed in the results section, which was detected in nine abstracts (9 of 25, 36%), was focusing on a positive secondary endpoint. A complete summary of spin strategies employed in the abstract results sections is presented in Table I.

**Spin in Conclusions.** Spin was found in the conclusion section of 27 (27 of 47, 57%) of the abstracts. The most common strategy, which was detected in eight abstracts (8 of 27, 29%), was claiming equivalence based on a negative endpoint. A summary of spin strategies employed in the abstract conclusions is presented in Table I.

### TABLE I.

<table>
<thead>
<tr>
<th>Characteristics of Spin in the Title and Abstract of Otolaryngology Randomized Clinical Trials.</th>
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<tbody>
<tr>
<td>Spin in the title</td>
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<tr>
<td>Spin in the results section</td>
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<tr>
<td>Focus on (+) secondary endpoint</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Verbiage implying numerical significance</td>
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<tr>
<td>Focus on (+) modified treatment population</td>
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<tr>
<td>Focus on (+) subgroup analysis</td>
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<tr>
<td>Spin in the conclusions section</td>
</tr>
<tr>
<td>Claim equivalence/noninferiority for a (-) endpoint</td>
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<tr>
<td>Claim benefit based on (+) secondary endpoint</td>
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<tr>
<td>Focus on another objective</td>
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<tr>
<td>Verbiage implying numerical significance</td>
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<tr>
<td>Claim benefit based on (+) subgroup analysis</td>
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<td>Focus on (+) modified treatment population</td>
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**Secondary Endpoints**

**Spin and Funding Source.** Twenty-three of the 47 included studies did not mention a funding source, with spin being detected in 15 (15 of 23, 65%) of those associated abstracts. A complete summary of abstracts with detected spin and the listed funding source is presented in Table II. We did not calculate an odds ratio due to low event rates.

**Spin and Trial Registration.** Of the 47 included abstracts, 20 (20 of 47, 42%) documented a trial registration in a clinical trial registry and included the trial registration number. Spin due to reporting bias was not detected in any of the studies. Of the 33 abstracts in which spin was detected, 15 (15 of 33, 45%) reported a trial registration number.

**DISCUSSION**

We identified spin in nearly three-fourths of the abstracts included in our analysis of the otolaryngology literature. Spin was most commonly found in the conclusion sections of these abstracts, with the most common strategy being to claim parity based on a statistically nonsignificant endpoint, followed by claiming clinical benefit based on a significant secondary endpoint. Spin was present in a majority of the included trials that were funded by industry; however, with the variability in overall numbers in each funding source category, this finding may be incidental. Additionally, no mention of funding source was made in a majority of the trials in which we detected spin. A majority of the trials that reported a trial registration number were found to have spin present in their abstracts. Our study is the first to evaluate spin in otolaryngology journals, and our findings mirror the results of studies found in the general medicine literature. In the field of analgesics, a study found that spin was frequent in the abstracts of analgesic clinical trials, affecting 47% of results and 42% conclusion sections. Additional studies have found spin in obstetrics and gynecology journals and the psychiatry literature, and a particular study investigating high-impact surgical journals found that the reporting and interpretation of results were frequently inconsistent with the raw data.

The first review of spin was conducted by Boutron et al. These investigators employed the help of experts...
from the Cochrane Statistical Method Group in defining and identifying spin in the general biomedical literature. Based on the feedback and insight received from these experts, they developed a classification scheme, which they then applied in their study. We adopted this same classification scheme in our study; that is, we defined spin exactly as Boutron et al.-defined spin. Our study differs from Boutron et al. by investigating only the abstracts of otolaryngology clinical trials. Since the Boutron study, there have been other investigations of spin in other areas of medicine. These studies were aggregated and evaluated in a systematic review of spin conducted by Chiu et al. Based on the findings of this systematic review, our study demonstrated comparable but higher rates of spin in the abstracts of included otolaryngology randomized trials with nonsignificant primary endpoints (70% in our study vs. 60.5% in the collated studies). This same systematic review also grouped studies by the definition of spin employed, and the Boutron et al. definition that we used in this study was most common (20 of 35 total included studies, 57.1%).

Minimizing the presence of spin in RCTs should be of great importance to the medical community, and we present some solutions to consider. For the detection of spin, it is essential that vital protocol data, such as the prespecified primary endpoint, are easily available for readers. These data allow readers to compare the current reported protocol to the original specified endpoint. Mandatory trial registration is a centralized way to present this information in a widely available format. In our study, less than half of the included trials had reported a trial registration number, making it difficult to determine what pretrial outcomes were being tested. Further research needs to be done to assess the level of trial registration that exists in otolaryngology journals. The use of reporting guidelines, such as the Consolidated Standards of Reporting Trials (CONSORT) statement for RCTs, is another potential way to minimize spin. For combating spin specifically in abstracts, we recommend adherence to the CONSORT for Abstracts, which was created in 2008. A recent study using the CONSORT guidelines found that the reporting of RCTs in high-impact otolaryngology journals is suboptimal and needs improvement. In 2004, a user’s guide was created on how to detect misleading reports in clinical research articles; this should be implemented and made widely available by journals. This step could help educate readers on how to analyze for spin. It is also possible that editors, authors, and peer reviewers have simply not been trained to detect the presence of spin, and such training must be implemented. Peer reviewers are particularly optimally placed to analyze for spin; however, they have known difficulty with detecting spin, particularly in abstract conclusions. No single method will eliminate all spin in the literature, but a combination of methods could prove to be the most effective solution for the spin present in otolaryngology RCTs.

Our study has several limitations and strengths that must be mentioned. By necessity, our assessment of spin involved a degree of subjectivity. Although we attempted to reduce the amount of spin through a standardized extraction method, it was impossible to completely eliminate it. We attempted to reduce the effect of this subjectivity through independent data extraction by two reviewers, with any disagreements being resolved through postextraction discussion until both reviewers came to agreement. If consensus could not be reached, then a third party was consulted. Another limitation is that several studies appeared to contain spin, but they lacked a clear definition of primary and secondary endpoints. Therefore, these studies were excluded based on our selected inclusion criteria. More spin may have been found if endpoints had been clearly defined in all RCTs. Lastly, although we recognized a trial as significant if it had a $P$ value of less than 0.05, we understand that information within RCTs should not be interpreted solely on binary statistical values. Finally, our findings are pertinent to otolaryngology RCTs alone. Further research is needed on other types of studies, and our results should not be generalized to different publication designs.

CONCLUSION

In conclusion, spin was common within our sample of otolaryngology RCTs. The next step is to determine what types of spin have the greatest effect on readers’ opinions and interpretations of RCT data. Evidence shows that spin has the potential to change clinician opinions of study outcomes, which could in turn have direct clinical implications. Our study was not designed to detect these implications, and further research must be directed at understanding if there is a downstream effect of spin on the creation of clinical practice guidelines and patient care in otolaryngology. Given our findings that the otolaryngology literature has slightly higher rates of spin than was found in a systematic review of spin, we recommend the careful evaluation of future otolaryngology clinical trial findings.

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