

Characteristics of Orthopedic Publications in High-Impact General Medical Journals

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abstract

Orthopedic studies are occasionally published in high-impact general medical journals; these studies are often given high visibility and have significant potential to impact health care policy and inform clinical decision-making. The purpose of this review was to investigate the characteristics of operative orthopedic studies published in high-impact medical journals. The number of orthopedic studies published in high-impact medical journals is relatively low; however, these studies demonstrate methodological characteristics that may bias toward nonoperative treatment. Careful analysis and interpretation of orthopedic studies published in these journals is warranted. [*Orthopedics*. 2017; 40(3):e405-e412.]

With health care reorganization, there is a movement toward identifying the orthopedic interventions that are highly effective and can be delivered at a reasonable cost.¹ To this end, there is increasing emphasis on the role of evidence-based medicine to better inform health care policy and the configuration of health care services.² Specifically, health policy experts have suggested that high-quality, carefully conducted investigations within orthopedic surgery will have the greatest impact for dictating health care policy and shaping how patients receive care.³

Given the increased prevalence of musculoskeletal illness, high-quality orthopedic studies are often published in a variety of scientific journals, including high-impact general medical journals. Traditionally, or-

thopedic studies published in high-impact medical journals have received high levels of public and health policy attention and the results and findings of these studies have been reported by national media outlets. As such, orthopedic studies published in high-impact medical journals may have the highest visibility and thereby the largest potential for ultimately influencing key stakeholders in the health care system (payers, providers, and patients). Furthermore, publication of orthopedic studies in general medical journals may be beneficial for educating nonsurgeon physicians on the benefits and risks of orthopedic interventions. This may be particularly important in future health care systems wherein general medical practitioners may dictate referral patterns for musculoskeletal problems.

However, medical journals may be subject to preferential reporting of orthopedic studies whereby only potentially controversial or surprising research findings are published. Such practices can lead to publication biases and contribute to poorly informed treatment and coverage decisions.⁴ The goals of the current study were to (1) determine the publication rate of orthopedic studies in the high-impact medical journals and (2) analyze the characteristics of the published orthopedic articles. The hypotheses were that there is a low incidence of orthopedic publications in premiere general medical journals and that the orthopedic studies published in these journals favor nonoperative treatment.

MATERIALS AND METHODS

Search Strategy

Studies published in 5 high-impact medical journals were screened: *Annals*

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of *Internal Medicine*, *Archives of Internal Medicine* (renamed *The Journal of the American Medical Association [JAMA]* *Internal Medicine* in 2013), *Lancet*, *JAMA*, and *The New England Journal of Medicine (NEJM)*. A total of 8093 research articles published in these 5 journals between July 2005 and July 2015 were screened for eligible orthopedic studies. A total of 798 articles were screened from the *Annals of Internal Medicine*, 1838 from the *Archives of Internal Medicine*, 1731 from *Lancet*, 1636 from *JAMA*, and 2090 from *NEJM*. Studies reporting on the outcome of orthopedic surgical intervention and on perioperative management strategies after orthopedic surgery were included. Perioperative pharmacotherapy, radiographic/diagnostic, and epidemiologic studies of the burden of musculoskeletal illness without discrete assessment of the impact of surgical intervention were excluded. A total of 39 studies (mean publication rate of 0.5%) were identified: 11 (0.6%) from *Lancet*, 9 (0.4%) from *NEJM*, 8 (0.4%) from *Archives of Internal Medicine*, 8 (0.5%) from *JAMA*, and 3 (0.4%) from *Annals of Internal Medicine*.⁵⁻⁴² These are the percentages of orthopedic studies compared with the other studies published in these journals during the search period.

Data Collection and Statistical Analysis

The following general demographic characteristics were abstracted from the included studies: journal of publication, country of study origin, study subspecialty, date of publication, number of authors, profession of lead/senior author, study type (randomized controlled trial [RCT], registry database, epidemiological, cohort analysis, and cost analysis), study level of evidence (I–V), study sample size, funding sources for individual authors and the overall study, conflict of interest status, and citation rates. Citation rates were obtained using a Google Scholar search. Studies published in 2015 were excluded from mean citation rate calculations.

Sixteen of the 39 studies (41.0%) were RCTs. Randomized controlled trials are considered the highest level of evidence, and the majority of the included RCTs (15 of 16; 93.8%) compared operative with nonoperative management. The authors secondarily screened these 15 RCTs for methodological parameters suggestive of bias: double blinding, control groups investigated, prestudy exclusion of potential surgical candidates performed at the discretion of the investigator, presence and proportion of crossover to surgical arm from nonoperative arm, intention to treat vs as-treated analysis, acknowledgement of study biases, and direction of study findings. They defined direction of study findings based on the study's findings regarding the benefit of surgery, with positive being surgery is better than nonoperative management, negative being no benefit to surgery over nonoperative management, and neutral being benefit identified to both surgery and conservative management. The quality of RCTs was graded using the Jadad scale.⁴³

Additionally, to better understand the characteristics of the high-impact journals, the authors reviewed each journal for its editorial board composition. They searched online for the primary specialty or specialty training attributable to each board member. A traditional “editorial board” publishing structure was not identifiable for *Lancet* and thus this journal was not included in the editorial board member search. Statistical analyses were descriptive. Means and rates were calculated where applicable.

RESULTS

General Demographics

All Included Studies. Of the 8093 medical journal articles screened, 39 (0.5%) met the inclusion criteria. Included studies were published between January 2006 and May 2015. *Lancet* (N=11; 28.2%) and *NEJM* (N=9; 23.1%) published the majority of the orthopedic studies. Nineteen studies (48.7%) were

derived solely from North America and 16 (41.0%) solely from Europe. The majority of the studies were level I RCTs (N=16; 41.0%), followed by prospective registry studies (N=14; 35.9%). Spine (N=16; 41%) and adult reconstruction (N=12; 31%) were the most frequently represented orthopedic subspecialties among all of the studies. A large number of studies received some form of governmental funding (N=30; 76.9%) or organizational funding (N=12; 30.8%) or had multiple funding sources (N=14; 35.9%). The mean number of citations for all of the studies was 245 at a mean of 4.8 years since publication (**Table 1**).

Randomized Controlled Trials. Among the included studies, 16 were RCTs. All 9 of the studies published in *NEJM* were RCTs, and this journal contributed the most RCTs to the evidence base (N=9; 56.3%). *JAMA* and *Lancet* each contributed 3 RCTs. The mean Jadad score for all of the RCTs was 3.4 (range, 3–5). Ten of the 16 RCTs (63%) were related to spine and 4 (25%) were related to sports medicine; there were no RCTs for adult reconstruction. The mean size of the study population among RCTs was 236 subjects. Europe and North America each contributed 6 RCTs (37.5%), while 3 (18.75%) were from multiple continents. A large number of RCTs received governmental funding (N=13; 81.3%), organizational funding (N=5; 31.3%), or industry funding (N=4; 25%) or had multiple funding sources (N=7; 43.8%). The mean number of citations for all RCTs was 433 at a mean of 5.3 years since publication (**Tables 1-2**).

Editorial Board Specialties

Among the high-impact medical journals, 57 editorial board members were identified. Nineteen (33.3%) editorial board members identified with internal medicine, 9 (15.8%) with cardiology, and 5 (8.8%) with medical oncology (**Table 3**). No board member was identified who had musculoskeletal specialty training or affiliation.

Table 1

Characteristics of Included Studies		
Characteristic	No. (%)	
	All Studies (N=39)	RCTs (N=16)
Journal		
<i>Lancet</i>	11 (28.2)	3 (19)
<i>NEJM</i>	9 (23.1)	9 (56)
<i>JAMA</i>	8 (20.5)	3 (19)
<i>Archives of Internal Medicine</i>	8 (20.5)	0 (0)
<i>Annals of Internal Medicine</i>	3 (7.7)	1 (6)
Geography		
North America	19 (48.7)	6 (37.5)
Europe	16 (41.0)	6 (37.5)
Asia	2 (5.1)	0 (0)
Australia	1 (2.6)	1 (6.25)
Multiple continents	1 (2.6)	3 (18.75)
Level of evidence		
I	16 (41.0)	16 (100)
II	8 (20.5)	-
III	12 (30.8)	-
IV	3 (7.7)	-
Study classification		
RCT	16 (41.0)	16 (100)
Registry	14 (35.9)	-
Cohort	6 (15.4)	-
Case	2 (5.1)	-
Epidemiology	1 (2.6)	-

Table 1 (cont'd)

Characteristics of Included Studies		
Characteristic	No. (%)	
	All Studies (N=39)	RCTs (N=16)
Study subspecialty		
Adult reconstruction	12 (31)	0
Hand	2 (5)	1 (6)
Pediatrics	1 (3)	0
Spine	16 (41)	10 (63)
Sports medicine	4 (10)	4 (25)
Trauma	4 (10)	1 (6)
Authors, mean	9	11.9
Surgeon as a leading author	15 (38.5)	9 (56)
Surgeon as a senior author	18 (46.2)	7 (43.8)
Funding source		
Governmental	30 (76.9)	13 (81.3)
Organizational	12 (30.8)	5 (31.3)
Industry	5 (12.8)	4 (25.0)
Institutional	3 (7.7)	2 (12.5)
Multiple	14 (35.9)	7 (43.8)
No funding	1 (2.6)	0 (0)
Studies with 1 or more authors personally funded by industry	23 (59.0)	13 (81.3)
Studies with a perceived conflict of interest	13 (33.3)	13 (81.3)
Total study citations, mean	245	433

Abbreviations: JAMA, The Journal of the American Medical Association; NEJM, The New England Journal of Medicine; RCT, randomized controlled trial.

Characteristics Associated With Bias

Of the 16 included RCTs, 15 compared surgical intervention with some form of nonoperative care and were included in subgroup analysis. Eight studies (53.3%) reported negative findings, 5 studies (33.3%) had positive findings, and 2 studies (13.3%) were neutral. Only 4 studies (26.7%) employed double blinding. In 11 of the 15 study protocols (73.3%), patients were prescreened out to surgical intervention by study investigators prior to randomization, and in 7 of these 11 studies, prescreening to surgery was done at the

investigators' discretion. In 13 of the 15 studies (86.7%), there was crossover from the nonoperative to the surgical arm of the study; the mean proportion of nonoperative patients crossing over to surgery was 33.2%. Nine studies (60.0%) reported only intention to treat analysis, none of the studies reported only as-treated analysis, and 6 (40.0%) studies reported both as-treated and intention to treat analysis. Among the 6 studies performing both types of analysis, 3 studies reported that as-treated analysis was discrepant to intention to treat analysis, with as-treated analysis revealing

surgical benefit that had not been evident in intention to treat analysis. Seven studies (46.7%) explicitly acknowledged selection bias as a study weakness (Table 4).

DISCUSSION

This study involved a review of operative orthopedic studies published in 5 high-impact medical journals. The authors confirmed their hypotheses—the rate of publication for orthopedic studies in these journals was low and there are characteristics among published studies that may suggest bias in the general

Table 2

Orthopedic Randomized Controlled Trials Published in Top Medical Journals (2005–2015)

Study Title	Author (Year)	Journal	Country	Comparisons
Surgical vs nonoperative treatment for lumbar disk herniation. The Spine Patient Outcomes Research Trial (SPORT): a randomized trial	Weinstein et al ¹⁶ (2006)	<i>JAMA</i>	US	Standard open discectomy vs usual nonsurgical care
Surgery versus prolonged conservative treatment for sciatica	Peul et al ⁶ (2007)	<i>NEJM</i>	Netherlands	Early surgery vs prolonged conservative treatment with surgery if needed
Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis	Weinstein et al ²⁰ (2007)	<i>NEJM</i>	US	Standard decompressive laminectomy (with or without fusion) or usual nonsurgical care
Surgical versus nonsurgical therapy for lumbar spinal stenosis	Weinstein et al ⁵ (2008)	<i>NEJM</i>	US	Decompressive surgery vs usual nonsurgical care
A randomized trial of arthroscopic surgery for osteoarthritis of the knee	Kirkley et al ¹⁰ (2008)	<i>NEJM</i>	Canada	Surgical lavage and arthroscopic debridement with physical and medical therapy vs physical and medical therapy alone
Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial	Wardlaw et al ¹³ (2009)	<i>Lancet</i>	8 European countries	Kyphoplasty vs nonsurgical care
Tubular discectomy vs conventional microdiscectomy for sciatica: a randomized controlled trial	Arts et al ⁴¹ (2009)	<i>JAMA</i>	Netherlands	Tubular discectomy vs conventional microdiscectomy
A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures	Buchbinder et al ⁸ (2009)	<i>NEJM</i>	Australia	Vertebroplasty vs a sham procedure
A randomized trial of vertebroplasty for osteoporotic spinal fractures	Kallmes et al ⁹ (2009)	<i>NEJM</i>	Multiple continents	Vertebroplasty vs a sham procedure
Surgery versus non-surgical therapy for carpal tunnel syndrome: a randomised parallel-group trial	Jarvik et al ¹⁴ (2009)	<i>Lancet</i>	US	Carpal tunnel surgery vs nonoperative care including hand therapy and ultrasound
A randomized trial of treatment for acute anterior cruciate ligament tears	Frobell et al ⁷ (2010)	<i>NEJM</i>	Sweden	Structured rehabilitation plus early ACL reconstruction vs structured rehabilitation with the option of later ACL reconstruction if needed
Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial	Klazen et al ¹⁵ (2010)	<i>Lancet</i>	Netherlands and Belgium	Percutaneous vertebroplasty or conservative treatment (medical treatment)
Surgery versus physical therapy for a meniscal tear and osteoarthritis	Katz et al ¹¹ (2013)	<i>NEJM</i>	US	Surgery and postoperative physical therapy vs a standardized physical therapy regimen (with the option to cross over to surgery at the discretion of the patient and surgeon)
Arthroscopic partial meniscectomy versus sham surgery for a degenerative meniscal tear	Sihvonen et al ¹² (2013)	<i>NEJM</i>	Finland	Arthroscopic partial meniscectomy vs sham surgery
Surgical vs nonsurgical treatment of adults with displaced fractures of the proximal humerus: the PROFHER randomized clinical trial	Rangan et al ¹⁷ (2015)	<i>JAMA</i>	UK	Surgical vs nonsurgical therapy
Surgery versus nonsurgical treatment of lumbar spinal stenosis: a randomized trial	Delitto et al ¹⁹ (2015)	<i>Annals of Internal Medicine</i>	US	Surgical decompression vs therapy

Abbreviations: ACL, anterior cruciate ligament; JAMA, The Journal of the American Medical Association; NEJM, The New England Journal of Medicine; UK, United Kingdom; US, United States.

Table 3

Primary Specialty of Editorial Board Members of High-Impact Medical Journals

Primary Specialty	No. ^a
Internal medicine	19 (33.3%)
Cardiology	9 (15.8%)
Medical oncology	5 (8.8%)
Pediatrics	4 (7.0%)
No medical background	4 (7.0%)
Geriatric medicine	3 (5.3%)
Infectious disease	3 (5.3%)
Endocrinology	2 (3.5%)
Nephrology	2 (3.5%)
Immunology	1 (1.8%)
Gastroenterology	1 (1.8%)
Genomic medicine	1 (1.8%)
Psychology	1 (1.8%)
Pulmonary	1 (1.8%)
Tropical medicine	1 (1.8%)

^aN=57.

medical literature toward nonoperative care. Specifically, a large number of RCTs preexclude surgical patients at the discretion of study investigators, show a high rate of crossover to the surgical arm, and do not account for this crossover because they perform only an intention to treat analysis. There also appears to be a higher prevalence of negative and neutral studies among general medical journals. The conduct and implementation of level I evidence in the form of RCTs is difficult, particularly when evaluating surgical interventions. There is a continued need for high-quality investigations such as the ones included in this study. However, the authors' review highlights potential areas for methodological improvements in future orthopedic RCTs and emphasizes the need for a more critical lens when evaluating orthopedic studies published in general medical journals. Such studies

Table 4

Methodological Characteristics Among Randomized Controlled Trials Comparing Operative and Nonoperative Treatments

Characteristic	No. ^{a,b}
Control group	
Primary physical therapy	3 (20.0%)
Usual nonoperative (physical therapy nonprimary)	6 (40.0%)
Sham	3 (20.0%)
Medical treatment	1 (6.7%)
Hand therapy	1 (6.7%)
Physical therapy with delayed surgery if failing physical therapy	1 (6.7%)
Double blinding	4 (26.7%)
Prestudy exclusion of potential surgical candidates	11 (73.3%)
Crossover from conservative to surgical arm during study	13 (86.7%)
Crossover proportion to surgical	33.2% ^c
Cohort analysis	
As-treated only	0 (0%)
Intention to treat only	9 (60.0%)
Both	6 (40.0%)
Selection bias explicitly stated as a weakness	7 (46.7%)
Study findings	
Positive	5 (33.3%)
Negative	8 (53.3%)
Neutral	2 (13.3%)
Concluded by authors that nonoperative management is preferred	8 (53.3%)

^aN=15.

^bPercentages do not total 100 due to summation error associated with rounding to 1 decimal place.

^cMean.

may influence health policy and clinical decision-making and ultimately will impact whether patients have access to certain interventions.

In this study, the authors identified characteristics common among the included RCTs that may suggest a trend toward biased outcome reporting. An interesting finding was that there was a high rate of crossover among included studies (33.2%). Crossover in RCTs is a phenomenon in which patients receive an intervention to which they were not originally randomized. The problem with high rates of crossover from nonoperative treatment

to surgery is that crossover is often one sided (ie, nonoperative to surgery only) and the positive effect of surgery is negated as the crossover rate approaches 50%. Intention to treat analysis analyzes patients based on the group to which they were originally assigned to preserve the value of randomization; however, it does not account for crossovers. In an as-treated analysis, patients crossing over from nonoperative to surgical treatment are analyzed as nonsurgical patients. However, the drawback of this method is that the benefit of randomization is lost in this scenario. As such, intention to treat anal-

yses have traditionally been considered superior because they may indirectly account for biases causing patients to cross-over from the group to which they were originally randomized. However, for non-surgical patients crossing over to surgery, the intention to treat analysis would rate their (potentially) successful outcome from surgery as being a good outcome in the nonoperative group. That is why the authors believe, despite the methodologic advantages of an intention to treat analysis, an as-treated analysis should also always be performed for studies comparing surgery with nonoperative care. It is increasingly noted that when as-treated analyses are incorporated, surgical superiority is demonstrated; therefore, it is ideal to present both analyses.³ In the current study, 60.0% of RCTs used intention to treat only, while 40.0% incorporated both intention to treat and as-treated analysis. In half of the studies using both types of analysis, as-treated analysis results were different from intention to treat results and indicated the superiority of surgical intervention.

Among the RCTs comparing surgical with nonoperative care, the authors found that the majority of these studies had negative or neutral findings. Defining the direction of study findings can be challenging; however, an accepted definition for a positive study finding is one in which the experimental treatment is favored over the standard of care, or the nonintervention group. In accordance with this definition, surgical intervention is typically deemed experimental compared with nonoperative care. Thus, positive study findings were those in which surgical intervention was found to be superior and negative study findings were those in which surgical intervention was not associated with any benefit. It has been well documented that positive study findings are the more common form of evidence reporting in both the medical and the surgical evidence base.⁴⁴ This phenomenon has been termed “selective publication bias”

and is concerning because it may influence the perceived efficacy of medical or surgical treatments, potentially leading to unnecessary interventions. In a study evaluating the direction of study findings submitted to the *Journal of Bone & Joint Surgery (American Volume)*, the authors⁴⁵ noted that 72.5% of studies were positive, 15.2% were neutral, and 12.3% were negative. However, the direction of study findings did not influence the likelihood of publication; thus, the authors concluded that the higher prevalence of positive findings in the *Journal of Bone & Joint Surgery (American Volume)* was attributable to preferential author submission of positive outcome studies. In the medical literature, one prior study similarly found an overwhelming trend toward the publication of positive outcomes. The authors⁴⁶ noted that among 74 Food and Drug Administration-registered drug studies, 38 had positive outcomes as assessed by the Food and Drug Administration and 37 of these were published. Among the remaining 36 with negative or neutral findings, these studies either were not published or when reaching publication had a positive outcome interpretation in conflict with the Food and Drug Administration’s conclusion. Given this well-known high prevalence of positive study outcomes in both the medical and the orthopedic literature, the high prevalence of negative/neutral orthopedic outcome studies in the top medical journals is interesting. Less is known about reverse selective publication bias (ie, a bias toward reporting negative/neutral study findings). Although positive publication bias remains problematic, the antithesis—a negative outcome reporting bias—can be similarly troublesome. It is unclear whether the high prevalence of negative orthopedic outcome studies in medical journals is the result of a lack of manuscripts with positive findings being submitted to these journals, systematic decisions by medical journal editors or reviewers not to publish positive studies, or possibly both.

Of the 5 medical journals reviewed, *NEJM*, *JAMA*, and *Lancet* contributed the largest proportion of orthopedic studies. Interestingly, these 3 journals appear to have differing publishing profiles regarding the types of orthopedic studies accepted for publication. The 9 studies published in *NEJM* were RCTs; interestingly, 7 of the 9 had negative or neutral study findings. Studies published in *JAMA* were primarily US database studies and RCTs. Studies published in *Lancet* (a British-based journal) included RCTs (notably, all 3 RCTs had positive study findings), small case series of cutting edge orthopedic technology, and registry updates from the National Joint Registry for England and Wales. Comparative assessment of these 3 journals suggests that *Lancet* has a publishing profile for orthopedic studies different from those of *NEJM* and *JAMA*. This may be a reflection of the British health care system, attitudes of the journal’s editorial staff, or both.

The impact of investigative funding sources and conflicts of interest in orthopedics has been previously studied. Prior studies have focused on industry interactions and a possible bias toward positive outcome reporting for studies and authors affiliated with industry.⁴⁷ Although a large number of the included RCTs had individual authors with industry affiliation (N=13; 81.3%), overall a small number of studies were funded by industry (N=4; 25.0%). However, only 50% of these industry-sponsored RCTs had positive study findings. The majority of the RCTs, however, did receive some form of governmental funding. Thirteen of the 15 RCTs (81.3%) comparing operative with nonoperative treatment received governmental funding; 10 of these 13 studies (76.9%) had neutral or negative study findings. Less is known about the role of governmental funding sources in engendering bias.

This study had several limitations. The authors reviewed published studies. Because they did not have access to studies

submitted to the journals, they are unable to comment on the impact of publication bias. It is plausible that orthopedic investigators with negative study findings preferentially submit their work to top medical journals, whereas investigators with positive findings submit to orthopedic journals. Further, without knowing how many orthopedic studies are submitted to the general medical journals evaluated, the authors cannot comment on the rate of publication in these journals. The authors screened only for operative studies; thus, the studies included in this review may not fully represent all of the orthopedic studies published in medical journals.

CONCLUSION

The authors found that the rate of publication for orthopedic studies in top medical journals was low and that high crossover rates were not accounted for. There was also a high prevalence of neutral/negative study findings. It is unclear whether this phenomenon is related to a lack of manuscripts with positive findings being submitted to these journals, systematic decisions by medical journal editors or reviewers not to publish positive studies, or both. Orthopedic studies published in top medical journals have a high impact and often receive national and international attention. Careful analysis and interpretation of these studies is warranted to appropriately influence health policy and inform clinical decision-making.

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