

Author disclosure of conflict of interest in vascular surgery journals

Thomas L. Forbes, MD, *London, Ontario, Canada*

Objectives: Advances in vascular surgery are increasingly technology-driven, and the relationships between surgeons and the medical device industry can be complex. This study reviewed conflict of interest (COI) disclosure in the vascular surgery journals regarding several selected technology-driven topics, including endovascular stent grafts (EV), carotid artery stenting (CAS), and peripheral arterial interventions (PI), to suggest further directions.

Methods: Authors' COI disclosures were reviewed from all clinical papers published in 2008 and 2009 in each of six vascular surgery journals, and pertaining to three selected topics (EV, CAS, and PI). Rate of COI disclosure was evaluated as a function of journal, topic, article type (randomized trial, case series, case report, review, or meta-analysis), and authors' region of origin. Secondarily, consistency of authors' disclosure was evaluated by reviewing papers by the same author and of the same topic.

Results: Six hundred thirty-five papers were reviewed from the six journals. A COI was declared in 125 (19.7%) of these papers. This rate differed between journals (range, 3.2%-34.1%; $P < .0001$). Rate of disclosure did not differ between topics (range, 12.8%-21.2%; $P = .12$), article type (range, 14.7%-30%; $P = .28$), or region of origin (range, 0%-33.3%; $P = .09$). There were 116 instances of the same author writing papers describing the same general topic. COI disclosure was consistent in the majority of these instances (72.4%), but inconsistent in 32 cases (27.6%). The most common ($P = .006$) inconsistencies involved the same type of article in different journals (46.9%), or in the same journal (25%).

Conclusions: Rates of disclosure of COI, and inconsistencies in disclosure in the vascular surgery literature are at least partially due to differences in journals' reporting policies, while a smaller proportion of these inconsistencies are due to individual author behavior. Journals should adopt a consistent requirement for a separate COI declaration where all relevant financial arrangements are disclosed. (*J Vasc Surg* 2011;54:55S-8S.)

Discussions regarding conflict of interest (COI) between the medical device industry and physicians are becoming increasingly common and intense. There is no question that these relationships can be mutually beneficial, and there are many instances of these collaborations resulting in advances in surgical technology and knowledge to the benefit of our patients.¹ However, these relationships can also lead to real or perceived conflicts that can undermine patients' trust in physicians,² as well as the independence of medical education³ and research.⁴⁻⁶ These truly can be complex relationships.

Many medical and surgical subspecialties have explored these issues in their published literature, including cardiac surgery,⁷ cardiology,⁸ gastroenterology,⁹ and, probably most extensively, orthopedic surgery.^{4,5,10-12} In the field of vascular surgery, these often competing interests were extensively explored at the Crawford Critical Issues Forum at the 2010 Vascular Annual Meeting in Boston. Speakers representing vascular surgery, the medical device industry,

regulatory bodies, government, and the legal profession expressed their views regarding the current status of these relationships.

In response to these issues, many major medical journals, including the *Journal of Vascular Surgery*,¹³ instituted mandatory reporting of any potential conflict of interest among authors several years ago. Most major surgical journals currently employ similar standards; however, reporting of COIs appears to be variable among different journals. There may be several explanations for this. The objective of this review was to examine possible inconsistencies or variability between authors reporting of COI among vascular surgery journals so that contributing factors might be recognized to arrive at suggestions for COI disclosure in the future.

METHODS

The tables of contents of six vascular surgery journals were reviewed for all issues published in 2008 and 2009. Three specific topics were the subject of this investigation as they represent major advances in surgical technologies, at least partially as a result of collaborations between physicians and industry. Papers chosen for subsequent review were limited to those describing endovascular abdominal or thoracic aortic stent grafts (EV), carotid artery stenting (CAS), or percutaneous interventions for peripheral arterial disease (PI). Other areas, including venous disease, were considered, but it was decided to restrict analysis to these three clinical areas as they represent a large proportion of papers published in the vascular surgery literature. Following a review of the methods section articles were classified as

From the Division of Vascular Surgery, London Health Sciences Centre and the University of Western Ontario.

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Reprint requests: Thomas L. Forbes, MD, Division of Vascular Surgery, London Health Sciences Center and the University of Western Ontario, 800 Commissioners Rd. E., E2-119, London, ON Canada, N6A 5W9 (e-mail: tom.forbes@lhsc.on.ca).

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Table I. Summary of methods

Topic	Type of paper	Origin of paper
Endovascular abdominal or thoracic aortic stent grafts	Randomized controlled trial	North America South America
Carotid artery stenting	Case series	Europe and Scandinavia
Peripheral interventions for peripheral artery disease	Case report	United Kingdom
	Review or meta-analysis	Australia and New Zealand Far East Africa

Table IIa. Conflict of interest disclosure by topic ($P = .12$)

Topic	Number of papers	Conflict of interest disclosure	%
Total	635	125	19.7
Endovascular abdominal or thoracic aortic stent	400	85	21.2
Carotid artery stenting	118	25	21.2
Peripheral interventions for peripheral artery disease	117	15	12.8

one of four types of papers: randomized controlled trial (RCT), case series, case report, or review/meta-analysis (Table I).

Each paper was then reviewed to determine whether the authors had disclosed a possible financial COI. The rate of COI disclosure was analyzed with respect to journal, topic, type of article, and authors' region of origin. Additionally, consistency of COI disclosure was determined by reviewing papers with the same corresponding or senior author on the same topic.

Statistical analysis was performed with χ^2 test for proportions with a $P < .05$ level of significance using Instat 3.06 software (GraphPad Software, San Diego, Calif). Results are presented such that the individual journals are not identified.

RESULTS

During this 2-year period, 635 papers were analyzed regarding author declaration of a COI. The majority of papers were case series ($n = 430$), while the remainder were RCTs ($n = 10$), case reports ($n = 129$), and reviews or meta-analyses ($n = 66$). The most common topic was EV ($n = 400$), followed by CAS ($n = 118$), and PI ($n = 117$). Half the papers originated from centers in North America ($n = 317$, 50%), while a third came from Europe and Scandinavia ($n = 211$, 33.2%).

Authors declared a COI in 125 of the 635 papers (19.7%). This did not differ when considering topic (range, 12.8%-21.2%; $P = .12$), type of paper (range, 14.7%-30%; $P = .28$), or geographic origin of the paper's authors (range, 0%-33.3%; $P = .09$). Although not statistically significant, there was a trend toward less frequent declara-

Table IIb. Conflict of interest disclosure by type of article ($P = .28$)

Article type	Number of papers	Conflict of interest disclosure	%
Total	635	125	19.7
Randomized controlled trial	10	3	30
Case series	430	92	21.4
Case report	129	19	14.7
Review/meta-analysis	66	11	16.7

Table IIc. Conflict of interest disclosure by region of origin ($P = .09$)

Origin	Number of papers	Conflict of interest disclosure	%
Total	635	125	19.7
North America	317	75	23.6
South America	3	1	33.3
Europe and Scandinavia	211	31	15.7
United Kingdom	64	11	17.2
Australia and New Zealand	15	5	33.3
Far East	24	2	9.2
Africa	1	0	0

Table IIId. Conflict of interest disclosure by journal ($P = .0001$)

Journal	Number of papers	Conflict of interest disclosure	%
Total	635	125	19.7
A	63	2	3.2
B	39	2	5.1
C	35	2	5.7
D	100	14	14.0
E	275	63	22.9
F	123	42	34.1

tion of COI in papers describing PI. Declaration of COI did differ among the six journals, however, ranging from 3.2% to 34.1% ($P = .0001$). Tables IIa-d summarize this information.

After cross-referencing the principal authors, there were 116 instances of the same author writing at least two papers with the same general topic (EV, CAS, or PI). COI disclosure was consistent (either disclosure or no disclosure) in 84 (72.4%) of these instances (Table III). There were 32 inconsistent sets of disclosures (27.6%), with the most common inconsistencies involving the same type of paper in different journals ($n = 15$, 46.9%) or the same journal ($n = 8$, 25%).

DISCUSSION

Most interactions between physicians and industry are beneficial to the advancement of science, and there are many examples to support this. Although research takes place in the laboratories of universities, hospitals, and com-

Table III. Comparison of disclosure of COI by authors of articles on same topic

<i>Same author/topic sets</i>	<i>Number</i>	<i>%</i>	<i>P</i>
Total	116		
Consistent COI	84	72.4	
Inconsistent COI	32	27.6	
Topic			
Endovascular abdominal or thoracic aortic stent grafts	28	87.5	
Peripheral interventions for peripheral artery disease	4	12.5	
Pattern			
Different journal and same type	15	46.9	.006
Same journal and different type	5	15.6	
Different journal and type	4	12.5	
Same journal and type	8	25	

COI, Competition of interest.

mercial enterprises, it is usually only following physician collaboration with industry that translation to beneficial therapy is achieved.¹ Many argue that these physician-industry relationships can be ethically managed and, in fact, are necessary for the advancement of medical science and patient therapies.¹⁴ When asked, patients may also recognize the necessity of these interactions and trust their physicians to manage these relationships, rather than government or regulatory bodies.²

Unfortunately, however, the lines can be blurred. What begins as a mutually beneficial and ethical relationship can deteriorate into a conflict of interest most commonly as a result of competing monetary issues and compensation. Either party, physician, and/or industry, can precipitate this, resulting in an erosion in the trust of physicians held by patients, students, and the public. In the pharmaceutical literature industry, employees have been listed as co-authors with increasing frequency,¹⁵ and a general association between medical and surgical clinical trial industry funding and statistically significant proindustry findings has been observed by some.⁶ A consistent and liberal disclosure policy is necessary for maximum transparency.

In the medical device-related disciplines, orthopedic surgery has been the most investigated specialty regarding physician payments by device manufacturers. There is no doubt that these financial relationships occur, but there has been concern regarding the accuracy of their reporting. In a recent study, lists of payments made to orthopedic surgeons by joint prostheses manufacturers were compared with author reporting of these payments at a major orthopedic national meeting.¹⁰ The disclosure rate of payments directly related to the topic of the presentation was 79.3%, with the most common reasons for nondisclosure being the author believing the payment was not directly related to the presentation (38.9%), or misunderstanding the reporting requirements (13.9%). In a similar paper describing the coronary stent literature, 83% of papers did not contain any disclosure statement whatsoever. Also, only 3% of authors who did disclose a financial relationship with stent manu-

facturers did so consistently in all their papers.⁸ Rather than representing fewer financial relationships between cardiologists and industry, these findings suggest a less strict reporting policy by cardiology journals and an underreporting by their authors.

The present study reviews the rate and consistency of COI reporting in the vascular surgery literature. This review was restricted to papers involving the device-related topics of EV, CAS, and PI. One-fifth (19.7%) of papers included a COI disclosure, which is a similar rate as that reported in the orthopedic⁵ and gastroenterology⁹ literature. Although there was a trend toward fewer disclosures in PI papers, there was no statistical difference between these three topics. Possible explanations for this trend include the relative recent growth of the PI industry, relative to stent grafts, such that these industry-physician relationships may not have developed yet to the same frequency or extent as other clinical areas with a longer history. That is, COI is declared less often with PI papers because it truly does not exist. In addition, it is possible that the primary author's specialty may contribute to the likelihood of COI existence and disclosure. Although not investigated as part of this study, it is proposed that vascular surgeons are more likely to author papers describing stent grafts, while nonsurgeons contribute more papers describing peripheral interventions. Whether author specialty is a determinant of the likelihood of a COI or its subsequent disclosure is yet to be determined and was beyond the focus of this paper.

Neither article type, whether it be a case report or RCT, or region of origin influenced this rate of COI disclosure. Half the papers were from North American authors, and several regions had few papers (ie, South America), but region of origin did not influence the rate of COI disclosure in this study. Rates of disclosure were consistent worldwide.

Rates of COI disclosure did differ, however, between the six vascular surgery journals, ranging from 3.2% to 34.1%. There are a number of possible explanations for this. First of all, although the six journals are general vascular surgery journals, the scope of publication differs slightly between them. Some of them could be seen as having a more technology-driven theme that might attract papers from authors who are more likely to work closely with industry. Secondly, the journals are of varying impact factors. Those with the higher impact factors might attract submissions from more senior or experienced authors who are more likely to have a relationship with industry based on the length and productivity of their surgical and academic careers. These possible explanations are the result of observations from this study, and data to prove them are beyond the scope of this study.

Another reason for the observed variation in COI reporting between the journals pertains to the journals' reporting guidelines and processes themselves. The COI disclosure processes of these journals include mandatory completion of separate authors' role and COI disclosure forms, mandatory inclusion of a statement of disclosure or

nondisclosure in a cover letter, or voluntary inclusion of a disclosure statement. Those journals requiring separate forms or statements tended to have higher rates of disclosure than those that did not, suggesting some confusion on the authors part as a result of these different processes.

In the vast majority of instances, COI disclosure was consistent when authors published more than one paper describing the same topic. Authors either consistently reported a COI or no COI in all papers in 72.4% of instances. Of course, it is difficult, if not impossible, to determine whether reporting consistency equals accuracy. In the remaining 27.6% of instances, there was inconsistency in COI disclosure by authors of papers with the same topic. Close to half of these inconsistencies (46.9%) were instances of the same type of paper in different journals, suggesting that journal reporting processes are contributory. In another quarter of the instances of disclosure inconsistency, the same type of article was published in the same journal. These instances may reflect author specific issues, such as confusion or uncertainty regarding the relevance of a financial relationship to a paper's topic.

This study has several methodological limitations. It is an observational study limited to a 2-year publication window and three topics specific to vascular surgery, so the results may not be generalizable to other areas. The study cannot comment on the extent or degree of COI as the observations were restricted to the presence or absence of a COI disclosure. Additionally, by the nature of a 2-year publication window and by restricting the study to six specific journals, the instances of multiple publications by the same authors are likely underreported.

Vascular surgery will continue to be a technology-dependant specialty with advances requiring collaboration between individual practitioners and industry. Although the term "conflict of interest" has negative connotations, these relationships are not inherently bad, but they do require accurate reporting so that readers themselves can determine their relevance or irrelevance. Disclosure of these relationships needs to be consistent and accurate to permit an unbiased interpretation of the literature. The differences in conflict of interest reporting between the different vascular surgery journals suggests the need for mandatory completion of a separate COI disclosure form for all journal articles. Some inconsistencies in COI disclosure will continue to be due to author issues, such as confusion over guidelines and processes or questions of relevance. In these instances authors should be encouraged to overreport, rather than fail to report, any possible or perceived conflict of interest.

CONCLUSIONS

Relationships between physicians and the medical device industry are necessary to ensure appropriate and safe

development of novel therapies. Whether these relationships constitute a conflict of interest should be determined by the readers, not the authors who should disclose all financial relationships with any possible relevance to the paper in question.

As journal reporting policies partially determine rate of disclosure, vascular surgery journals should adopt a uniform requirement for a separate financial relationship reporting document for all paper submissions in order to minimize author confusion.

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