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Buried Treasures: Unpublished Results of Industry-Sponsored Neurointerventional Trials

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Editorial Office Communications. The editorial office of *INR* will be modified to reflect the cooperation of the 2 journals, and its functioning unit will be changed to facilitate access and integration in line with current practices at *AJNR*. This should lead to a user-friendly submission and exchange of homogeneous information between the journals, signifying their alliance. It will facilitate a strategy enabled to accommodate the highest caliber submissions to be published in the most appropriate environment.

Neuroradiology/Interventional Neuroradiology Benefits. From its beginning some half a century ago, neuroradiology has included and fostered research in all aspects of imaging of the central nervous system. This included advances in neuroimaging and new techniques proposed not only by neuroradiologists but also by practitioners with a background in the various aspects of the neurosciences. Advances in neuroimaging facilitated the feasibility of image-guided therapy and treatments performed by specialists in neuroimaging. This in turn resulted in the evolution and establishment of interventional neuroradiology as a distinct specialty. At the same time, interventional neuroradiology benefited greatly from the participation of neuroscientists with different backgrounds (neurology, neurosurgery, and radiology), which enhanced the specialty and facilitated its introduction into the realm of multidisciplinary patient care. Guidelines for standards of training and standards of practice in interventional neuroradiology will benefit greatly from endorsement by neuroradiology. A close link between neuroradiology and interventional neuroradiology will ensure advances in the field are the result of high-quality scientific exchange of information and lead to excellence in patient care.

AJNR's Perspective

At the beginning of this year, Dr. terBrugge approached the American Society of Neuroradiology with the idea of establishing a collaboration between *INR* and *AJNR*. This idea was first floated by ASNR's Publications Committee and afterward gained approval by the Executive Committee. A letter of agreement was developed, and I flew to Toronto to personally speak to Karel and discuss the details of our collaboration. Karel responded to our ideas in his usual gentlemanly form, and I feel very pleased that our agreement was signed with enthusiasm by all.

Operating Principles. *AJNR* receives a significant number of interventional-related submissions, which are handled by 2 dedicated Senior Editors. Because of limited space, many excellent manuscripts are rejected; this is particularly true of Case Reports. The *INR/AJNR* collaboration opens the possibility of offering publication to a wider number of these papers. *AJNR*'s subscriber base lies predominantly in the Americas while *INR*'s enjoys wide readership in Europe, Asia, and Oceania. We are working out discounted fees for subscribers and advertisers in both journals. Dr. terBrugge and his editorial team are working with *AJNR*'s Web designer to modify their Website so it will have a similar functionality to that of *AJNR*. A link to *INR* may already be found on our Website. Last, our future series of Special Collections dealing with interventional articles will benefit from containing articles from both journals.

Editorial Office Communications. Dr. terBrugge and Dr. Timo Krings will serve as liaisons between their journal and ours, a fact clearly identified in our masthead. Similarly, Drs. Strother and Cloft will serve as members of the *INR* editorial board. Our submission Website now has the ability to generate letters to corresponding authors advising them that their submissions should be sent to *INR* when they cannot be accommodated by *AJNR*. In this fashion, we should be able to track the number of articles that benefit from our collaboration and determine their eventual fate. All of these activities would not be possible without the involvement of our editorial staff. Collaboration between staff will provide *INR* the administrative/editorial experience of *AJNR* in setting up their Website, streamlining submission processes, and obtaining *INR*'s own Impact Factor.

Neuroradiology/Interventional Neuroradiology Benefits. In this era of turf disputes and fragmentation of our specialty, I am very satisfied that the first steps have been taken to ensure the worldwide presence of *AJNR* in association with interventional neuroradiology. Sharing subscriber bases will help both journals reach a wider audience. Because *INR* has the strongest international support within interventional neuroradiology and *AJNR* is the pre-eminent diagnostic neuroradiology journal, our agreement heralds a new era of global collaboration and understanding between radiologists and related scientists. I want to thank ASNR's Executive and Publications Committees, especially Dr. Gordon Sze, for their support. I cannot think of any other "American" imaging-related society that has done anything similar to what we are attempting with this collaboration. At this early stage, it is difficult to speculate where this activity will lead to in the future, but with good will and enthusiasm from all parties involved, Dr. terBrugge and I feel very optimistic and invite all of our readers and authors to participate and embrace this alliance.

K. terBrugge

Editor-in-Chief

Interventional Neuroradiology

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EDITORIAL

Buried Treasures: Unpublished Results of Industry-Sponsored Neurointerventional Trials

Clinical trials are conducted to advance medical knowledge and thereby improve patient care. The results of clinical trials are generally published in the peer-reviewed medical literature, which provides physicians with easy access to this important information. Physicians can then assess the trial results themselves, decide how to incorporate them into patient care, and plan future research. It is through this peer-reviewed collection and dissemination of information that our collective medical knowledge advances. If trial results are not

published in the peer-reviewed literature, then this process of advancing knowledge breaks down. We, therefore, find it disturbing when the results of industry-sponsored clinical trials of neurointerventional therapies are not published in the peer-reviewed literature.

Industry sponsors have an inherent conflict of interest regarding publication of trial results. They will tend to encourage publication of favorable results and discourage publication of unfavorable results. This tendency is known as publication bias and has been well documented as a real phenomenon.¹ Unlike an industry sponsor, physicians and patients can benefit from access to all trial results, regardless of whether the results are favorable or unfavorable. If we are unable to access information from trials with unfavorable outcomes, then it is difficult to analyze the results and incorporate them into decisions about patient therapy and future research.

There are varying degrees of unavailability of trial results. For example, trial results are sometimes presented at an open meeting of physicians but then not subsequently published. The Schneider Wallstent trial is such a trial.² This trial randomized patients with symptomatic carotid stenosis to undergo carotid angioplasty and stent placement or carotid endarterectomy. The trial was stopped early for safety concerns because of excessive complications in the angioplasty and stent-placement arm. Obviously, this was not a favorable result for the corporate sponsor. While some important information is released when results are presented at a meeting, it is not an adequate substitute for publication in a peer-reviewed journal. The peer-reviewed literature is the foundation of our collective learning experience in medicine. Research results are subjected to the peer-review process to provide a theoretically unbiased referee who will attempt to identify any serious bias or unsubstantiated claims or conclusions. The peer-review process allows editors to identify which articles should be published and to make improvements in these articles via revisions. Once published, the articles are then permanently accessible to physicians through libraries.

Another example of an unpublished trial is the Acceleration of Connective Tissue Formation in Endovascular Aneurysm Repair (ACTIVE) registry, which was a multicenter study of the Matrix detachable coil (Boston Scientific, Natick, Mass), which occurred immediately after the product was released on the US market in 2002 following US Food and Drug Administration (FDA) clearance. A newsletter from Boston Scientific did publicize some of the ACTIVE results.³ Obviously, such a newsletter would not be expected to be very critical in its analysis of the results, nor would the newsletter be as accessible to the community as would a peer-reviewed journal article. One might reasonably speculate that the ACTIVE results were not published in the peer-reviewed literature be-

cause a positive interpretation of the results would not stand up to the peer-review process.

More recently, trial results not published in the peer-reviewed literature have appeared in the "Instructions for Use" included in the packaging for neuroendovascular devices. Some results of the US Multicenter, Randomized, Controlled Study Comparing the Performance of Onyx (ethylene-vinyl alcohol copolymer; ev3, Irvine, Calif) and Trufill (*n*-butyl cyanoacrylate [*n*-BCA]; Cordis, Miami Lakes, Fla) in the Presurgical Embolization of Brain Arteriovenous Malformations (AVMs) are available in this format. This trial was conducted to evaluate the safety and effectiveness of Onyx compared with *n*-BCA for the presurgical treatment of brain AVMs. The trial was completed in 2003, and Onyx was approved by the FDA in 2005. If nearly 6 years have passed since the completion of this study, it seems highly unlikely that it will be published in the peer-reviewed literature.⁴ The US Multicenter Onyx Aneurysm Study is another study for which results are available only in the "Instructions for Use." Onyx HD-500 was approved by the FDA in 2007 as a humanitarian use device for cerebral aneurysm treatment. Perhaps the results of this trial will be published eventually, but as more time passes, publication probably becomes progressively less likely.

To help ameliorate the problem of unpublished results, the FDA Amendments Act of 2007 now mandates that results of trials be disclosed through a data base that will be publicly accessible via the internet at www.clinicaltrials.gov.⁵ This legislation will certainly help to improve public access to data of interest to physicians and patients. Hopefully, publication of clinical trial results in peer-reviewed literature will also occur more consistently in the future because the peer-reviewed publication process is essential to complete and critical evaluation of the data.

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