Letters to the Editor

Applaud the Novel Intrathecal Baclofen Trialing Method: Time to Raise the Bar!

To the Editor:

It is with great interest that we read the article by Harned et al, "An Introduction to Trialing Intrathecal Baclofen in Patients with Hemiparetic Spasticity," published in the 2011 September/October issue of *Pain Physician* (1). We are very much enlightened by the new approach as well as the painstaking effort employed by the authors in conducting their intrathecal (IT) baclofen trials for patients with complicated spasticity involving both upper and lower extremities. The novelty is that, instead of administering a single shot of IT baclofen at a commonly accepted arbitrary dose, i.e., 50 µg or up to 100 µg, the authors made use of a short term indwelling IT catheter, thus allowing wider range of IT baclofen through continuous infusion. The trial was done in an inpatient setting where the reduction of Modified Ashworth Scale (MAS) in affected limbs and the preservation of strength in the unaffected limbs were recorded. With this unique approach, the authors were able to capture those responders that would have been missed with routine single shot trialing method. It appears that it will improve the chance of achieving positive IT baclofen trials in the subpopulation of patients with severe, complex spasticity syndromes involving both upper and lower extremities due to augmented response rate brought about by the new trial approach.

At our tertiary interventional pain clinic, we sometimes receive referrals for placement of IT baclofen for treating intractable spasticity. Under rare circumstances (see below), we had tried placing a tunneled epidural catheter for epidural baclofen infusion when IT trial was not of an option. About 3 years ago, we encountered a case of severe spasticity of bilateral lower extremities due to multiple sclerosis in a middle aged woman unresponsive to extremely high dose of oral baclofen (60 mg 3 times a day by the referring neurologist). The patient adamantly refused considering an IT baclofen trial due to her previous experience of a "monster headache" following lumbar puncture. A focused literature review did reveal some prior successful experience of epidural baclofen for intractable spasticity by others, presumably because baclofen is lipophilic enough to pass through the dura into cerebrospinal fluid (CSF) (2). When IT baclofen trail was not an option for our patient, we decided to perform an epidural baclofen infusion trail as outpatient, which turned out to be a success. The patient subsequently had a permanent IT pump implanted and to this day she has been doing well. As a matter of fact, we are preparing a case report of this alternative approach using outpatient baclofen epidural infusion trial in lieu of IT trial, in patient when IT trial was not an option, as well as a long-term follow up study (3 years) following permanent implant. We wonder whether Dr. Harned et al encountered cases when IT baclofen trial was not an option.

In our clinic, we have performed hundreds of opioid epidural infusion trials safely as outpatient, in patients with intractable chronic pain, prior to placing permanent IT pumps. We have found neuroaxial opioid infusion trials, when done properly in the outpatient settings, gave more pertinent information on how patients did in their activities of daily living (ADLs). We believe same principle applies to spinal or epidural baclofen infusion in patients with spasticity. The patient's own experience or the direct observation from the caretakers during patient's ADLs at home may be more clinically meaningful than the Ashworth Spasticity Score obtained while lying in a hospital bed during the patient's inpatient IT baclofen trial. We have seen cases where paraplegic patients were utilizing part of their LE spasticity for facilitating pivot transfer, when their legs became totally flaccid with IT baclofen infusion, they lost their abilities to transfer. We wonder if Harned et al would consider extending their IT ba-

clofen trials a bit longer to cover an outpatient phase of a couple of days where the benefit of IT baclofen could be thoroughly assessed when patients were performing their ADLs at home.

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Necessity and Implications of ICD-10: Facts and Fallacies

To the Editor:

In an effort to inform the readership of Pain Physician about the impending conversion to the ICD-10 system, we published a detailed review article on point 1. The final line of the paper was a recommendation to" postpone implementation of ICD-10 and focus rather on core issues of improving care and access."

The Centers for Medicare & Medicaid Services will require all health professionals and facilities to transition to ICD-10 by October 2013. ICD-10 is viewed as being more nuanced and providing a greater level of detail for what had led to an injury or illness. ICD-9 has 14,000 codes. As outlined in the article, implementing ICD-10 nationally will require a tremendous allocation of resources. The upcoming change would require practices to learn 69,000 new codes for billing purposes.

The American Medical Association (AMA) apparently agrees. During the 65th House of Delegate Interim Meeting of the AMA that occurred on November 15, 2011, 2, delegates adopted a policy to work to stop implementation of the new diagnosis coding set ICD-10. Alabama and Mississippi delegations, the American Association of Clinical Urologists and the American Urological Association introduced the resolution to stop ICD-10 implementation.

"The implementation of ICD-10 will create significant burdens on the practice of medicine with no direct benefit to individual patients' care," said AMA President Peter W. Carmel, MD. "At a time when we are working to get the best value possible for our health care dollar, this massive and expensive undertaking will add administrative expense and create unnecessary workflow disruptions. The timing could not be worse, as many physicians are working to implement electronic health records into their practices. We will continue working to help physicians keep their focus where it should be -- on their patients" (2).

On February 16th, 2012 Health and Human Services Secretary Kathleen G. Sebelius announced that HHS will initiate a process to postpone the date by which certain health care entities have to comply with implementation of the ICD-10 system. Sebelius said … "We have heard from many in the provider community who have concerns about the administrative burdens they face in the years ahead. We are committing to work with the provider community to reexamine the pace at which HHS and the nation implement these important improvements to our health care system (3)."

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3. www.cms.gov/ICD10/Downloads/HHSPressReleaseICD10final321612.pdf

3 Things to Consider Before Relying Solely on Point of Care Tests for Determining Benzodiazepine Use in Chronic Pain

To the Editor:

We read with interest the article titled "Comparative Evaluation of the Accuracy of Benzodiazepine Testing in Chronic Pain Patients Utilizing Immunoassay with Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) of Urine Drug Testing" (1). Having provided the analytical information used as the basis for the article, we felt it important to relate information to your readers that may be of further benefit.

Although the dangers of benzodiazepine use and overuse among the pain patient population were clearly stated, it was suggested that patients who have been prescribed benzodiazepines who test positive for them on point of care tests do not require additional testing by LC-MS/MS. We disagree with this suggestion and offer the following to support our position.

As many of your readers who use point of care devices are aware, the immunoassays on these devices only indicate whether the patient is positive or negative for the benzodiazepine class. That is, point of care tests cannot determine which benzodiazepine the patient is taking or, more importantly, if the patient is taking multiple benzodiazepines.

We are not suggesting that it is necessary to send all positive benzodiazepine point of care specimens for further testing; some providers may wish to only send specimens from specific patient populations, such as those who exhibit aberrant behavior, or those at high risk for controlled substance abuse (2).

An unexpected urine drug test (UDT) result demonstrating positive results for multiple benzodiazepines provides an opportunity to further explore the potential underlying reasons. Numerous reasons may exist for this type of unexpected UDT result, including self-treatment of anxiety with an alternative benzodiazepine, self-treatment of another symptom (e.g., insomnia) with an alternative benzodiazepine, and/or duplicate therapy due to lack of patient knowledge regarding which medications are benzodiazepines (e.g., lorazepam for anxiety, temazepam for sleep). In many of these cases patients may not fully recognize the potential risk. However, point of care tests alone will not identify such use or outcomes; only further laboratory testing will provide information that elucidates potentially dangerous duplicate therapy (prescribed or nonmedical use) with benzodiazepines.

To reference the same data from the study your article was based on, of the patients who were positive for the benzodiazepine class by Point of Care immunoassay, when tested by LC-MS/MS, 15% were found to be taking additional benzodiazepines compared to those reported as prescribed by their provider.

Those patients may not wish for their physician to know they are self-medicating with benzodiazepines other than what they are "supposed" to be taking, but it is certainly in their best health interest for their physician to know.

On another note, in your article it is suggested that patients who test negative by point of care device for benzodiazepines, and who have not been prescribed those drugs, do not require further laboratory testing by LC-MS/MS. We believe the data may suggest otherwise, and this leads to the second point of use to your readers.

In the study upon which your article was based, 6% of the patients who were not prescribed benzodiazepines were found to be taking them (1). This percentage increased by 50% to 9% of patients when analysis was conducted by LC-MS/MS. (Note: in our studies of hundreds of thousands of patients we find 15% of the population to be using nonprescribed benzodiazepines.) This suggests that somewhere between 9 and 15 out of every 100 pain patients are taking non-prescribed benzodiazepines.

In light of this demonstrated ability to reduce the incidences of false negative results at the point of care, we believe physicians should carefully consider whether sending specimens for further testing by LC-MS/MS may be the better course to minimize patient risk, at least for certain higher risk patients.

The third point of information we'd like to men-

tion is that the immunoassays used in point of care tests do not tell the physician which benzodiazepine a patient is taking, only that he or she is positive or negative for the benzodiazepine class of drugs. As the physician treating patients with the potent and delicate mix of opiates and benzodiazepines, it would seem that identifying which benzodiazepine a patient is taking would be of as much value as knowing exactly which opiate the patient is taking. This can only be achieved by conducting further analysis with LC-MS/MS. Why?

We already established the value to the patient's health by identifying the use of nonprescribed benzodiazepines. Beyond this, knowing specifically which benzodiazepine the patient is taking provides the physician with valuable information when reviewing the patient's medications with them to determine if they are getting adequate relief from their symptoms.

As stated in the article about which this letter is being written, drug testing adds to the cost of care. However, in a newly released study, urine drug testing, including laboratory quantification, demonstrates the positive cost benefit of UDT as determined by LC-MS/MS (3).

It is ultimately up to each physician to assess on a case by case basis the clinical value, risks, and benefits for conducting urine drug testing. As the title of this letter indicates, we have offered your readers 3 evidence-based considerations when making the most informed decision possible when testing for benzodiazepines.

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In Response: 3 Things to Consider Before Relying Solely on Point of Care Tests for Determining Benzodiazepine Use in Chronic Pain

To the Editor:

We appreciate Dr. Pesce's and West's comments on the manuscript. As they have illustrated, they were involved in the laboratory testing of the data of our publications (1-3). It appears that, they contend, based on 5% to 9% of patients using alternative benzodiazepine, essentially we should send all the tests to the lab.

For this, they also quote a study conducted by Laffer et al (4) which is part of Millennium Research Institute, part of Millennium Laboratories. This is considered not based on evidence and as promoting the urine drug industry by many. Further, a recent manuscript essentially shows that urine drug testing is not the practice of medicine; rather, it is a business model for profit centers (5).

Overall, considering the issues related to exploding health care costs and physicians' ability to provide any type of service based on the costs, it is essential to take a conservative approach with patient's history and drug testing results performed in the office. Even though,drug testing has become a cottage industry costing numerous health care dollars and resulting in significant curtailing of access to these drugs, a cost-effective and clinically effective approach is the one we have suggested in our manuscript (6).

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Does the Diagnosis of Spondylolisthesis Matter?

To the Editor:

We read the article by Stephan Klessinger with much interest (Radiofrequency Neurotomy for Treatment of Low Back Pain in Patients with Minor Degenerative Spondylolisthesis; *Pain Physician* 2012; 15:E71-E78 (1). The author has tried to establish the efficacy of radiofrequency neurotomy in patients with degenerative spondylolisthesis where zygapophyseal joint(s) are the predisposing factor. There are some important issues that need to be addressed. The objective of the study is inappropriate, which gives an improper direction to the whole study including the conclusion.

1. In the discussion the author writes, "It is known that these patients might have sources of pain other than just the zygapophysial joints. In particular, spinal canal stenosis is often present, which causes symptoms not treated by medial branch neurotomy…The second pathology which is often interlinked with degenerative spondylolisthesis is disc degeneration. Discogenic pain is also not treated by medial branch neurotomy." Considering these statements, titles like "Radiofrequency Neurotomy for Treatment of Low Back Pain of Zygapophyseal Joint Origin in Patients with Minor Degenerative Spondylolisthesis" would have been more appropriate and specific.
2. It is stated in the Methods that "The level of spondylolisthesis was always included in the radiofrequency neurotomy," whereas in Table 1, Characteristics of spondylolisthesis, radiofrequency neurotomy, pain relief and follow-up, patient #39 has a spondylolisthesis level of L3/4, although RF neurotomy was performed on L4/5/S1. Then what about L3? It is not quite evident from Table 1 what is exactly meant by "RF neurotomy" level? Is it the nerve level, or the level of vertebral transverse process?
3. In Fig. 2B, needle position should have been more medial. Unlike cooled RF, in thermal RF every millimeter matters; furthermore, preprocedure sensory/motor stimulation of medial branches or postradiofrequency EMG of multifidus have not been performed; therefore, the possibility of wrong techniques cannot be ruled out for the failures.
4. The term "radiofrequency" needs a little more elaboration. Throughout the study "lumbar radiofrequency neurotomy" has been mentioned. If this implies medial branch ablation, that should have been stated unambiguously. A radiofrequency procedure can also target a facet joint, disc, or sympathetic ganglion. RF neurotomy in the context of the present article should mean thermal RF only, but since there are 3 different types of RF (conventional, pulsed, cooled), it is better to mention the specific one.
5. These very statements "This is the first study to determine if radiofrequency neurotomy is effective for patients with degenerative spondylolisthesis and low back pain…To compare the success rate with the literature is impossible, because this study is the first available study" seems to be grossly inapt. Numerous published studies have attempted to establish the efficacy of RF neurotomy of the medial branch in facet joint pain. Of course they have not separately analyzed any subgroup with "facet joint pains with minor degenerative spondylolisthesis"; but those cases were not excluded either (2-4). This could be because of the simple fact that once facet joint pain has been established by dual diagnostic block, then irrespective of whatever is associated with it, RF should give the same result, at least for the short-term.

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In Response: Does the Diagnosis of Spondylolisthesis Matter?

I appreciate the useful comments to my article about radiofrequency neurotomy in patients with degenerative spondylolisthesis. The suggested title is good. Concerning the radiofrequency technique, I would like to refer to the Methods section. The type of radiofrequency, of course, is important. It can be found in the article together with details about the temperature, time of lesion, and so on. The needle position is very important. In each level, several lesions were performed with slightly different needle positions (the image is only one example); this is also mentioned in the text.

I would like to focus my answer to the last aspect of the letter. The question is whether the possibility exists that there might be a different pain source in addition to the zygapophysial joints. Assuming patients have zygapophysial joint pain typically in isolation, then it would not matter if the patient has a whiplash injury, a fracture, a herniated disc, a spondylolisthesis or a condition after surgery or something else and no subgroups for studies are needed. The only one criterion for considering a radiofrequency neurotomy must be complete pain relief after medial branch blocks. But is the reverse circuit also valid, that if another source of pain (for example after fracture of a vertebra or in spinal canal stenosis) is known, zygapophysial joint pain can be excluded, because zygapophysial joint pain exists only in isolation?

In contrast, assuming multiple sources of pain are possible at the same time, differential diagnosis of zygapophysial joint pain, and therefore the findings of examinations (including MRI), become important. Because more than one pain source exists, it is now no longer taken for granted that patients with different diagnoses have the same results after radiofrequency neurotomy. It is very useful to form subgroups of patients, for example with spondylolisthesis, in which different pain sources are conceivable. Unfortunately, with more than one pain source it is not possible to claim for complete pain relief after medial branch block an radiofrequency neurotomy.

In this study a subgroup of patients with spondylolisthesis and pain of zygapophysial joint origin was formed. The study allows an assessment of the prospects of success of radiofrequency neurotomy in patients with low back pain and degenerative spondylolisthesis. And because radiofrequency neurotomy is not an established therapy for back pain in patients with degenerative spondylolisthesis, these results are new and not to be found in the mentioned studies.

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In errata

The correct author order for the Letter to the Editor published in the Pain Physician 2012;15;95-96. Kyphoplasty for the Treatment of Vertebral Compression Fractures with Anterior Vertebral Wall Destruction: How Can We Do It Better? is:

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