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Letters

To the Editor:

Re: Suh SI, Koh SB, Choi EJ, et al. Intracranial hypotension induced by cervical spine chiropractic manipulation. Spine 2005; 30: E340–2.

As with most case reports, Dr. Suh's recent communication regarding cervical spine manipulation advances the hypothesis that manipulation of the cervical spine could have induced intracranial hypotension in a 36-year-old woman. When such instances are raised, it is critical to be able to clearly establish that the procedure, as yet undefined, unmistakably preceded the onset of the intracranial hypotension and cerebrospinal fluid leakage reported, in accordance with Hill's criteria for distinguishing causality from association.[1] The fact that this patient presented with neck and shoulder pain 4 days previous to the manipulation does raise the possibility that a spontaneous event was taking place, the frequency of which concerning cervical artery dissections has been shown to occur in both hospitals and community settings at frequencies as much as 10 times greater than that attributable to cervical manipulation.[2,3]

Finally, it is imperative that both the caregiver and the technique clearly be identified, given the fact that those administering manipulations have on occasion been incorrectly and possibly systematically identified as chiropractors but in fact lack the proper training and credentials to be capable of safely delivering a cervical manipulation.[4] To have been truly informative, this communication should have specified both the precise nature and frequency of manipulations performed such that follow-up effective investigations could have been performed. To simply brand and stigmatize the intervention as "chiropractic manipulation" without the necessary attributes is as unproductive as labeling the use of drugs as "medication" or a spinal laminectomy as "surgery."

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To the Editor:

Re: Zucherman JF, Hsu KY, Hartjen CA, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. Spine 2005; 30: 1351–8.

We read with great interest the article by Zucherman *et al* (*Spine* 2005; 30: 1351–8), in which they demonstrate at 2 years postintervention that the interspinous process decompression system (X STOP) device affords superior outcomes and equal safety to nonoperative therapy. At our center, we aim to practice and teach within an evidence-based framework, and, accordingly, our resident reading list is composed primarily of Nachemson and Jonsson's *Neck and Back Pain*,[1] which provides a summary of "best available evidence" up to the year 2000, supplemented with *Spine* articles from the "Randomized Trial" and "Health Services Research" sections, as well as Level One articles from *The Journal of Bone and Joint Surgery* American and British volumes, and metaanalyses from other sources. I do not know what to tell our residents about X STOP and look to the authors for insight.

After publication of this article, we did a simple Internet search engine query for "X-Stop and FDA." The same data presented in this article were presented to the Food and Drug Administration (FDA), where the panel reviewing the device recommended it "Not Approvable," meaning it was thought that the data DID NOT provide a reasonable assurance that the device was safe, *or* reasonable assurance HAD NOT been given that the device is effective (note: emphasis is per the FDA recommendations).

The FDA panel cited several concerns, including, but not limited to: (1) the block randomization used could potentially be used to select patients more likely to respond to the device; (2) outcomes in both groups were significantly worse than expected, which calls into question the validity of the power calculations; (3) results from one particular center were clearly su-

perior to results from other centers; (4) overall effectiveness of the device was not shown in the majority of the clinical study population; (5) concerns with long-term effectiveness (longer than 2 years) were noted; and (6) concerns regarding the need for radiographic or other objective evidence of the device's (mechanical) mechanism of effect on the spine in patients were raised.

We are all hopeful that some alternative for patients with stenosis will be found. Surgery appears to work well in select patients,[2] but many in this age group are unable to undergo an operation because of comorbidities or simply wish to avoid an operation. In addition, nonoperative alternatives such as epidural injections have been of limited value.[3] In light of 2 recent *Spine* articles drawing attention to outcomes and industry support[4,5] coupled with other recent hopeful technologies, such as IDET, being less hopeful with independent assessment, we look forward to the authors' response to the FDA concerns and an independent evaluation of outcomes for this technology.

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