

Mauricio Diaz

From: Mauricio Diaz [m.diaz@hansamed.net]
Sent: Friday, July 23, 2010 5:01 PM
To: 'jadaletters@ada.org'
Subject: Re: Occurrence of paresthesia after dental local anesthetic administration in the United States
Attachments: image001.gif

Importance: High

Dear Sirs,

I read with interest the article "*Occurrence of paresthesia after dental local anesthetic administration in the United States*" (July 1 2010, Volume 141, Issue 7). This paper seems to indicate that 4% drugs are significantly more likely to cause this adverse reaction than others.

I personally find these conclusions both misleading and unsubstantiated by scientific evidence.

I'd like to point out an important concept that seems to have been disregarded by both the authors, as well as by the reviewers of the article in question: The information source for this article comes from the Quarterly Data Extracts from the FDA's ADVERSE EVENT REPORTING SYSTEM (AERS). All of these packages contain a "README.DOC" file that, in "*Section B. CAVEATS*" states:

*"There are some important things to keep in mind when reviewing or analyzing AERS data: **For any given report, there is no certainty that a suspected drug caused the reaction.** This is because physicians are encouraged to report suspected reactions; however, the event may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or simply occurred by chance at that time. **Accumulated reports cannot be used to calculate incidence (occurrence rates) or to estimate drug risk. Comparisons between drugs cannot be made from these data.**"*

Figure 2 in the article indicates that lidocaine has a market share of 58% and articaine of 14%. This is not accurate, and may just represent the AVERAGE usage between 2000-2008. Articaine has significantly grown its market share in the USA.¹

So, if the usage of articaine has progressively increased, why haven't the reports followed suit? If the data is voluntary, incomplete, delayed and/or inconsistent, how can anyone derive any scientific conclusions from it? Should one choose which parts of the article are factual and which are not?

Contrary to this paper, a recently published meta-analysis of randomized controlled trials comparing lidocaine and articaine concludes that "*articaine is a superior anaesthetic to lignocaine for use in routine dental procedures*", and the author also could not find definitive evidence that articaine increases the risk of non-surgical postoperative paresthesia.²

The Department of Anesthesia at the University of Toronto, regardless of repeated articles on the subject, has not been able to scientifically prove that articaine represents a risk for the dental patients.

Despite their allegations, the market share for articaine in Canada consistently **grew from 37.84% in 1993 to 44.20% in 2007**, surpassing lidocaine (39.70%) by almost five percentage points.³ Also, articaine now represents around 30% of the USA market ... despite the litigious environment in this country.

Evidently, the clinical experience of the dentists using articaine regularly, does not correlate to the conclusions of articles such as the one in question.

Finally, to only find a **TOTAL of 226 paresthesia reports out of over 3.1 BILLION cartridges** injected (as per the article), truly borders on splitting atoms. This number would be equivalent to the total population of China, India and all of Europe put together, having a village with only 226 individuals affected by this condition.

As Malamed has previously expressed: *“There is absolutely no scientific evidence available to support the claim that articaine is associated with a greater incidence of paraesthesia (or stated more correctly, is more neurotoxic) than other local anesthetics.”*⁴

1. Pogrel MA. Permanent nerve damage from inferior alveolar nerve blocks: an update to include articaine. J Calif Dent Assoc 2007;35(4):271-273.
2. Katyal V. The efficacy and safety of articaine versus lignocaine in dental treatments: a meta-analysis. J Dent. 2010 Apr;38(4):307-17. Epub 2009 Dec 16.
3. Gaffen AS, Haas DA. Retrospective review of voluntary reports of nonsurgical paresthesia in dentistry. J Can Dent Assoc 2009;75(8):579.
4. Malamed SF: Articaine vs. Lidocaine: the author responds (letter) JCalif Dent Assoc 35:383, 2007.

Dr. Mauricio Diaz

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