

Dr. Mark Donaldson - Here's A Novel Direct Injection Buffering Technique for Local Anesthetics

Chiraz:

Hello and welcome to CDA Oasis, my name is Chiraz Guessaier. In a recent article published in Compendium last summer, Dr. Mark Donaldson and Dr. Jason Goodchild studied a new direct injection chairside buffering technique for local anesthetics. They state that there are benefits in buffering local anesthetic solutions using a simple hand mixing technique. So we have invited Dr. Mark Donaldson to tell us more, to ask him about this technique and how you as a dentist could benefit from it. By now you know who Dr. Donaldson is, he is our pharmacology expert and 2019 CDA Friend of Dentistry. Dr. Donaldson, thank you very much for taking the time to speak with me today. Welcome again to CDA Oasis.

Dr. Donaldson:

Absolutely. Thank you for having me, Chiraz.

Chiraz:

So, briefly, why did you undertake this study or why did you write the article?

Dr. Donaldson:

Yeah, so you know, one of my other full-time jobs is of course a research and you know, the idea of buffering local anesthetics is not a new one. In fact, it's been in the literature for I would say greater than 30 years, greater than 50 years perhaps and it's also been something that we do very commonly in medicine, but it has some tremendous utilization in dentistry. In fact, the alkalization or buffering of dental local anesthetics not only raises the pH of our very acidic local anesthetics to physiological pH where they are much more effective. It's a well-documented technique that also results in improved clinical benefits, faster onset of local anesthesia, perhaps more profound local anesthesia. And so a much more comfortable situation for the patient as well as from, you know, a practitioner standpoint it in fact can increase patient throughput.

Dr. Donaldson:

So you have happier patients. Your appointments tend to go a little smoother, perhaps a little faster. And the downstream effect really is a win-win and then actually another win. So, the study that we're referencing just now, which is a novel direct injection technique, is actually a follow-up to a study we did a few years ago and had also published in Compendium, that was under the support of Dentsply. So, the first study in buffering, what we did was we took a look at two existing devices that are available here in the United States. So one is called Anutra, that's a product that's available primarily on the East coast and another device on the West coast here is known as Onset, by a company called Onpharma. I don't work for either of these companies.

Dr. Donaldson:

I think it's interesting that they both sort of came out at the same time. But the reason I bring the story up is because those are the two FDA approved devices for chairside buffering techniques. And you know, whether you like those products or not, the fact of the matter is in bringing their products to

market they had to submit to the FDA essentially their formula, you know, what is it that they were using to buffer local anesthetics to make them more successful. And so, I really do want to give kudos to those companies because they set the pathway for us to do our investigation. Now, what they showed us originally was their secret sauce. Their secret sauce showed that a 9 parts local anesthetic combined with 1 part of sodium bicarbonate 8.4%, when you combine those at chairside you are able to produce a buffered local anesthetic that again was much more effective, had a faster onset, more profound local anesthesia and a much better patient experience.

Dr. Donaldson:

Now, both that Onset product and that Anutra product are only FDA approved for lidocaine 2% with 1:100,000 epinephrine and unfortunately there are six other local anesthetics that a lot of dentists use. Some are plain solutions, which probably don't require buffering, but there are other non-plain solutions. Articaine is a very good example of a common local anesthetic with [inaudible] agent which really could benefit from buffering, but in the United States those devices had not yet been approved. So with the help of Dentsply, we set up a bench top experiment to use that 9:1 ratio in order to buffer all commercially available local anesthetics across multiple samples and what we found was in that 9:1 ratio, you could in fact get all local anesthetics very, very close to physiological pH by buffering them in that 9:1 ratio and that these were going to be much more effective, essentially almost pain-free type injections for patients that gave more profound local anesthesia and again a better patient experience.

Dr. Donaldson:

Now the original study was called the "remove and replace" study because essentially what you're doing is you're taking that to that cartridge, In fact, I have one here, you take that cartridge of local anesthetic and what you're doing is you are removing out of the top end where the diaphragm is, you're removing 0.18 milliliters of the local anesthetic and you are replacing that with 0.18 milliliters of sodium bicarbonate, commercially available sodium bicarbonate. So, you remove, you replace and you shake, shake, shake and go ahead and inject the patient. Very, very effective across all local anesthetics that we tested. So, so that was great news. And while that was great news, as we felt, in the real world that's a little clunky and I know that's not really a medical term, but I think you get my meaning that removed and replaced.

Dr. Donaldson:

And so we stepped into this second approach, which could mean perhaps a direct injection approach, making the process of chairside mixing, chairside buffering much less onerous. And so if you were to take a look at most local anesthetic cartridges such as the one I have in my hand, most people that have seen them, you know, they recognize that there's a little bit of headspace in the top of these cartridges. And so rather than removing and replacing, given the fact that there's this available headspace, could you just inject directly some type of a buffering agent and again, shake, shake, shake, go ahead and inject? And this would be the direct injection technique. So, we did this across, again, multiple samples, all the local anesthetics commercially available in the United States and there's seven of those. And we did them at different varying ratios.

Dr. Donaldson:

So, we did the 9:1 which has been published and recognized by the FDA. We did it at a 19:1, which meant that we were only going to be introducing 0.09 millilitres and we did it in an 18:1 just because it's

much easier to measure that on a graduated syringe, 0.1 millilitres being added directly into this. Now, there's one sort of management suggestion that I would make, since you're not removing and replacing, as you go ahead and inject a little bit extra 0.1 millilitres of sodium bicarbonate into that diaphragm, that you may just want to sort of keep your finger or thumb over the other end because that's where that stopper is. And while the stopper is not going to shoot out by you adding some pressure at one end, it just I think is more of a comfort measure in case you feel it starting to move.

Dr. Donaldson:

So the addition, the direct addition of 0.1 millilitres of 8.4% sodium bicarbonate to any local anesthetic, giving you an 18:1 ratio by direct injection, allows you to eliminate some of the steps that we originally had suggested with that "remove and replace". And this new direct injection technique can be done very, very quickly. Essentially one step right there chairside. Go ahead and inject and the patient gets much more profound local anesthesia that tends to last a little bit longer as well, in almost every case. Now, this work was important because it's an original work. Nobody has ever done this type of a trial before. But what's so interesting is that in the Journal of the American Dental Association, just a couple months after our study came out, there was a published analysis showing that the buffering of local anesthetics, if practitioners are not currently doing this, they should consider, because based on all the evidence to date, buffered local anesthetics can improve the overall profundity of local anesthesia by up to three fold.

Dr. Donaldson:

So, this is something that's definitely new in dentistry, although, you know, some practitioners have been using it for a long time now, but the idea of mixing or doing a chairside buffering prior to injection not only results in a better and more comfortable patient experience, maybe not only offers faster patient throughput, but at the end of the day, based on current evidence, it's the right thing to do. And so, I greatly appreciate the fact that we were able to do this original scientific study to justify and give practitioners the tools, the methodology in how to do this. But you know, how nice is it to have other investigators at the same time come up with a publication that underscores the importance of this. So I'm very excited about it.

Chiraz:

Well, it validates what your what your findings are, Right?

Dr. Donaldson:

Exactly. Yeah. And in fact, there was a, the highest level of medical evidence, which is known as a meta analysis, and in fact the Cochrane group, which you're probably familiar with, studied and published a meta analysis roundabout the buffering of local anesthetics. And their conclusion was, essentially, it's very, very safe. There's never been any problems in patients and given the nothing but benefits, which greatly outweigh any safety concerns, this should be a common practice.

Dr. Donaldson:

All right. Since you remarkably answered all my questions related to the study, what are the implications for dentists? What should they keep in mind from our conversation?

Dr. Donaldson:

Yeah. So, the first thing to keep in mind is that you cannot buy buffered lidocaine off the shelf right now. And I think that always concerns practitioners because you know, we would like things to be as simple as possible.

Dr. Donaldson:

And so why do I have to go through this remove and replace or this direct injection technique just prior to administering local anesthetics. That interrupts my day. Well, the fact of the matter is it's a very unstable solution. When you mix sodium bicarbonate with a local anesthetic, that mixture can actually be effervescent. Now in the clinical trials that brought Onset market, this was actually a benefit. Because normally when we are about to inject a local anesthetic into a patient, you know, we'll tell them that they're going to feel some type of pinch or prick as, as the beveled needle of that syringe penetrates tissue. Well, when you buffer your local anesthetic, because that is an unstable effervescent mixture, as you go to inject your local anesthetic that bevel needle is actually slightly blunted by a carbon dioxide molecule.

Dr. Donaldson:

So, a carbon dioxide bubble actually comes out of the end of that, blunting the effect. So instead of patients feeling that sharp beveled needle, that bubble of carbon dioxide blends that. And in greater than 98.5% of patients that received buffered local anesthetic they said they never felt the pain of the injection. So, I think that that's a great sort of chemical piece to understand. You know, we cannot currently buy commercially available buffered lidocaine for dental use, because of the unstable nature, but we have tried to make it as simple as possible with this new direct injection technique to mix it chairside and then go ahead and administer patients right away. Certainly, this is not going to upset or slow down your schedule. And I think the benefits to the patient in truly providing painless dentistry is going to, you know, really be a practice builder.

Chiraz:

Great advice, great tips. Great conversation as usual, Mark. Thank you so much for coming to Oasis and speaking with me today. I really appreciate it.