Sedation & Anesthesia in Dental Practice LOCAL ANESTHESIA

"30+ YEARS OF HITS, MISSES AND NEAR MISSES"

The New Hampshire Dental Society Concord, New Hampshire November 9th, 2018

> Mel Hawkins, DDS, BScD AN Dentist / Dentist Anesthesiologist

Toronto, ON, Canada

DISCLOSURE

Mel Hawkins

is a Scientific Advisor/Consultant for dentist enquiries for two (2) *competing* local anesthetic manufacturing companies in the U.S.A.:

- Septodont Inc., Lancaster, PA and
- Carestream Dental, Rochester, NY.

No shares, stocks or ownership. No marketing or sales involvement. Not employed by either. Reimbursed quarterly.

> The New Hampshire Dental Society November 9th, 2018

AGENDA

Anatomy, Technique of Blocks, Road Blocks, More Blocks

2 What can go wrong? and What to do about it?

3 A Few Tips and Tricks

PART

1

Anatomy and Technique

BLOCKS, ROAD BLOCKS and NORE BLOCKS

THE ELUSIVE McDibular BLOCK ...millions and millions served . . .



Compiled various sources-Hawkins-2016

Relationship of:



Reasons for Failure

Anatomical variations

- Hard tissue anatomy
- Soft tissue anatomy
- Connective tissue
- Neurovascular anomalies

Anatomy of the Mandible: Hard Tissue



Anatomy of the Mandible: Hard Tissue



3 Major Factors:

- Internal oblique ridge / Ramus flare
- Sphenomandibular fascial barrier
- Risks: Nerves

Arteries



The distance between the internal and external oblique line of the mandible varies. Adapted from Dr. N. B. Jorgensen

MANDIBULAR NERVE

Ster Port

12-15-0 ST.

MEDIAL ASPECT

MIDDLE MENINGEAL

AURICULOTEMPORAL NERVE

MAXILLARY ARTERY (INTERNAL MAXILLARY)

INFERIOR ALVEOLAR NERVE

LINGUAL NERVE

SPHENOMANDIBULAR LIGAMENT

STYLOMANDIBULAR LIGAMENT

ARTICULAR DISK

ARTICULAR TUBERCLE

JOINT CAPSULE

AND ARTERY

Netter

Grant's Atlas of Anatomy

JAWS CLOSED

Histology

Pterygomandibular Triangle: Histology





Horizontal X-S, Conventional I.A.N.Block

Courtesy: Dr. G. Gow-Gates, Dr. J. Watson

University of Sydney Australia



Horizontal X-S, level of Gow-Gates Mandibular Block

Courtesy: Dr. George Gow-Gates, Dr. J. Watson

University of Sydney Australia

"Conventional" Inferior Alveolar Block

vs. a "mandibular block"

Conventional Advantages

- Intra-oral landmark for **113 years**
- Practitioner acceptance for **113 years**
- Fast onset if accurate and no neural aberrance, as in grade B and C anesthesia problems (14%)

Conventional Disadvantages

- Increased vascularity
- Anatomical variance
- Macroglossia
- Paresthesia mechanical lingual claims experience X 2
- (Long) buccal nerve "block"



"Chin on the Chest" Syndrome





open the Arvay





Coronoid Notch

Definition:

Greatest indentation depth on the anterior border of the ramus

QUESTIONS?

Akinosi Closed Mouth Mandibular Block

Vazirani 1960 Akinosi 1977

AKINOSI - Advantages

- Mouth closed less threatening
- Macroglossia bypasses tongue



AKINOSI - Disadvantages

- Vision impaired
- Difficult to gauge depth in children
- Flaring ramus + heavy internal oblique ridge (I.O.R.)
- Zygomatic ridge over teeth #3, #14
- #1, #16 buccally extruded + prominent tuberosity = geometrically unfavorable









Tuberosity



Hawkins JM, Local Anesthetic Techniques and Adjuncts, Chapter 13: Pain & Anxiety in the Dental Office WB Saunders 2002

Hawkins JM, Local Anesthetic Techniques and Adjuncts, Chapter 13: Pain & Anxiety in the Dental Office WB Saunders 2002
Hawkins JM, Local Anesthetic Techniques and Adjuncts, Chapter 13: Pain & Anxiety in the Dental Office WB Saunders 2002

Clinical Technique



Identify Maxillary Mucogingival Junction









AKINOSI

What can go wrong?

Akinosi Summary

| Onset | 5 - 10 minutes – block 3 minutes - soft tissue |
|----------------|---|
| Characteristic | Varies. Generally anterior lip, tongue first. Depends on trifurcation location |
| Duration | 1 - 1.5 hours pulpal Soft tissue-variable |
| Key Advantages | Children, apprehensive patient acceptance Fits "pre-injection" or "injectable topical" concepts |

QUESTIONS?

Gow-Gates Mandibular Block

Condylar Neck or High Ramus Block



<image>

Utilizing External Landmarks

An Intraoral Approach

Gow-Gates: Advantages

Perceptible end point with:

Vascularity Risk of nerve damage

Good buccal nerve anesthesia? YES!



Gow-Gates: Disadvantages

- Mouth must be **wide open**
- Extra-oral landmarks
- Post-injection, stay open 2 minutes
- Hemostasis needs to be added



Anatomical Considerations

eonardo Da Vinci



V3 foramen ovale to the mandibular foramen



Hawkins JM, Local Anesthetic Techniques and Adjuncts, Chapter 13: *Pain & Anxiety in the Dental Office* WB Saunders 2002



Graphic Courtesy of Dr. George Gow-Gates



Graphic Courtesy of Dr. George Gow-Gates

Clinical Technique

















Gow-Gates Summary

| Onset | 5 - 15 minutes |
|-------------------|---|
| Characteristic | posterior ⇔ anterior onset "wave" |
| Duration | 1 - 1.5 hours pulpal Soft tissue-variable |
| Post-op analgesia | 0.5% bupivacaine 1:200K epinephrine ⇒ 2 carpules [®] |

Mel Hawkins, DDS, BScD AN, Toronto, ON Canada

QUESTIONS?



PART

2

What can go wrong? and What to do about it



Infiltration of Mandibular Molars

Buccal and Lingual

Lingual Infiltration Summary

| Where | Apical to mucogingival junction ⇒ unattached, dark red gingiva |
|-----------------|---|
| How | 2-3 mm submucosal Bevel faces bone |
| Characteristics | Tissue balloons and blanches Patient tolerance |
| Volume | 0.3 - 0.7 ml. 4% articaine HCL 1:100K epi |
| Onset | 4 – 6 min |

Mel Hawkins, DDS, BScD AN, Toronto, ON Canada



Local Anesthetic News:

Pregnancy

Cover Story





Dental Treatment Safety with Local Anesthetics during Pregnancy 572

> Hagai, A, Diav-Citrin, O, Shechtman, S, Ornoy, A, JADA 146(8) Aug 2015

Pregnancy Safety

- A prospective, comparative observational study by the Israeli Teratology Information Services* (**TIS**), 1999 2005
- 210 pregnant patients were exposed to dental treatment, including local anesthetics
- 112 (53%) in 1st trimester
- vs. control group = 794 pregnant patients were not exposed to any dental treatment or local anesthetics

* Hagai A et al, Pregnancy outcome after in utero exposure to local anesthetics as part of dental treatment: A prospective comparative cohort study, JADA 146(8), Aug 2015

Pregnancy Safety

- The rate of major anomalies was not significant between the two groups.
- There was no difference in the rate of miscarriages, gestational age at delivery, or birth weight.

Hagai A et al, Pregnancy outcome after in utero exposure to local anesthetics as part of dental treatment: A prospective comparative cohort study, JADA 146(8), Aug 2015
Safest local anesthetics during pregnancy and breast-feeding:

- Lidocaine and prilocaine are FDA pregnancy risk category B
- All others are FDA pregnancy risk category C

U.S. Food and Drug Administration pregnancy risk factor definitions.*

| CATEGORY | DEFINITION |
|--|---|
| A | The results of controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of risk in later trimesters), and the possibility of fetal harm appears remote |
| В | Either the results of animal reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women OR |
| | the results of animal reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester and there is no evidence of risk in later trimesters |
| C | Either the results of studies in animals have revealed adverse effects (teratogenic, embryocidal or other) on the fetus and there are no controlled studies in women OR results of studies in women and animals are not available; drug should be given only if the potential benefit justifies the potential risk to the fetus |
| D | There is positive evidence of human fetal risk, but the benefits of use in pregnant women may be acceptable despite the risk (for example, if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective) |
| x | Results of studies in animals or humans have demonstrated fetal abnormalities or evidence of fetal risk based on human experience, or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit; use of the drug is contraindicated in women who are or may become pregnant |
| * Sources: U.S. Food and Drug Administration. ^{8,20,21} | |

(!!)

Safest local anesthetics during pregnancy and breast-feeding:

- Lidocaine and prilocaine are B
- All others are C
- Risk of methemoglobinemia with **topicals** (especially esters: benzocaine, tetracaine) and injectable prilocaine
- Epinephrine is OK!

Pregnancy: Safety- Local Anesthetics

Epinephrine is a catecholamine, which normally is present in the body, with **no** clear evidence of increased risk of malformation when used during pregnancy with local anesthetics.

> Hagai, A, Diav-Citrin, O, Shechtman, S, Ornoy, A, JADA 146(8) Aug 2015

Conclusions:

The use of dental local anesthetics, as well as dental treatment during pregnancy, **does not** represent a major teratogenic risk.

Hagai A et al, *Pregnancy outcome after in utero exposure to local anesthetics as part of dental treatment: A prospective comparative cohort study*, JADA 146(8), Aug 2015



Despite the reassuring considerations...

 Dentists are still reluctant to perform dental treatment for pregnant patients

and

 Women are still reluctant to receive dental treatment during pregnancy.

Hagai A et al, Pregnancy outcome after in utero exposure to local anesthetics as part of dental treatment: A prospective comparative cohort study, JADA 146(8), Aug 2015



Local Anesthetic News:

Reversal Agent

OraVerseTM Phentolamine Mesylate Injection

"Reversing" Local Anesthesia

Phentolamine Mesylate

reverses SOFT TISSUE ANESTHESIA ONLY

Phentolamine Mesylate is NOT a LOCAL ANESTHETIC reversal agent 13% of pediatric patients receiving IANB suffer post-treatment traumatic injury to soft tissues.

College C, Feigal R, Wandera A, Strange M. Bilateral versus unilateral mandibular block anesthesia in a pediatric population. Pediatr Dent. 22(6):453-457, 2000.



Adults and Adolescents: 60 Minute Efficacy Data

Time to Recovery of Normal Lip Sensation



Mandible

- **54.8%**; p<0.000 Phentolamine mesylate accelerates the return to normal sensation by **85 minutes**
- 41% phentolamine mesylate patients fully recovered in 60 minutes
- 7% for control patients

Pediatric patients also recover sensation in half the time

- Median time to recovery of normal lip sensation compared to control was reduced by:
 - 120 minutes (67%) in the mandible
 - 53 minutes (47%) in the maxilla



Source: Tavares M, Goodson JM, Studen-Pavlovich D, and colleagues. Reversal of soft-tissue local anesthesia with phentolamine mesylate in pediatric patients. JADA 2008;139(8):1095-1104. Copyright ©2008 American Dental Association. All rights reserved. Excerpted by permission.

Dosing

Easy to Dose

- 1:1 cartridge ratio to local anesthetic with a vasoconstrictor using identical injection site
- Maximum recommended dose
 - 2 cartridges for adults & adolescents 12 years of age and older
 - 1 cartridge for patients 6-11 years of age and over 66 lbs.
 - ½ cartridge for children 6 years of age or older weighing 33-66 lbs.



Potential complications

Needle-related:

• Trismus

Paresthesia



OraVerse TM

Now sold in sleeves of ten (10)



Phentolamine Mesylate

Ora Verse TM Cost?

OraVerse

NE MESYLATE) INJECTION

\$8/cartridge

NDC 1500-0101-00



Local Anesthetic News:

Buffering Agents

Performance Limitations of Current Anesthetics

- Onset Time
 - Time for body to buffer anesthetic
- Analgesia
 - Is No pain attainable? Always?
- Injection Pain

Stinging is a concern for patients

Clinical Study Data Pulpal - IANB

Percentage of Participants Profoundly Numb at 2 Minutes



71% of the participants receiving buffered anesthetic achieved pulpal anesthesia in under two minutes





Clinical Data – Pain Free Injections



44% of buffered anesthetic patients experienced zero injection pain



6% of traditional anesthetic patients experienced zero injection pain



From: Malamed S, Falkel M, Decreasing anesthetic injection pain using an automated dental anesthetic buffering system: A prospective, randomized, double-blind, crossover study, Draft for Publication, 2011

Clinical Data – Patient Preference



72 % of patients rated Onset[®] as **the most** comfortable injection



From: Malamed S, Falkel M, Decreasing anesthetic injection pain using an automated dental anesthetic buffering system: A prospective, randomized, double-blind, crossover study, Draft for Publication, 2011

30-Minute Time Course, Pulpal Analgesia, IANB



Buffering of Local Anesthetics

► Mixing Pen settings:

Falkel M & Goeltz J, Buffering, it's not just for lidocaine anymore, Dentistry Today, Nov. 2015 **ONSET® MIXING PEN:** dial settings for local anesthesic formulations

2% Lidocaine 1:100,000 Epinephrine

For 2% Lidocaine 1:100,000 EPI for all lower blocks dial

2% Lidocaine 1:100,000 Epinephrine

2% Lidocaine 1:50,000 Epinephrine

4% Articaine 1:100,000 Epinephrine

4% Articaine 1:200,000 Epinephrine

3% Mepivacaine

4% Prilocaine

4% Prilocaine 1:200,000 Epinephrine

For all infiltrations with Lidocaine & all other formulations dial



Onset[®] by On**ph**arma[®]

The exchange volume is only 0.18 ml.

The first and only chair side approach for precision buffering of local anesthetic Onpharma Nad BRIXIN Onpharma Onpharma^{*} 1 Onset Onpharma-Sodium Bicarbonate Inj.,8.4%,USP Neutralizing Additive Solution 4 CARTRIDGES **Bicarbonate Solution Cartridge Connector** Mixing Pen

\$55.00 / day based on X9 use

\$299.00 Not autoclavable

Buffering of Local Anesthetics

- Released February 2015
- An anesthetic buffering device and a multi-dose delivery syringe
 - Uses medical multi-dose anesthetic vials
 - Contain preservative methylparaben: increased potential for allergic reaction?



The Anutra Syringe Multiple Doses. One Syringe.

Larson CE, Methylparaben – an overlooked cause of local anesthetic hypersensitivity, Anesth Prog, 1977 Cashman AL & Warshaw EM, Parabens: a review of epidemiology, structure, allergenicity, and hormonal properties, Dermatitis, 2005



Local Anesthetic News:

Topical Anesthetics

Topical Anesthetics

Product Analysis

Topical Anesthetic: Compromises



Topical Anesthetics

- What do you do if you KNOW that the area can't be isolated (saliva, tongue), or
- The topical won't penetrate into tissue far enough to cover a deeper block?

Topical Anesthetics

Patients expect the use of a topical anesthetic!

Dr. Kit Weathers Endo Magic[®] Founder's Technique! Griffin, GA.

Lidocaine Viscous

FDA announces Box Warning Required

Product Analysis: Lidocaine HCI



"Should not be used for teething pain"

Product Analysis: Oraqix[®]







3

A FEW

TIPS & TRICKS BY TRIAL AND FAILURE!

CONVENTIONAL MANDIBULAR ANESTHESIA


Poor opening





Chin toward the ceiling



Head position consistent Patient supine and Roll of gravity?



Scissors prop or Mouth *rester*

Prop or "rester"

Right side goes with right side



Bevel Orientation – faces mid-sagittal plane this way

 \bigcirc

but deflects this way



Volume Considerations

- Amount given / amount available
- Time for diffusion
- Neuroanatomy (penetrable diameter)



How many 'carps' ?



How many 'carps'

 Enough
 > 1 ?

 Better/Best
 = 2 ?

 Too many
 < 4 ?</td>

for a block

Mean Number of Carps



Leonard M, Local Anesthesia Volume and Success Rates JADA Vol. 126(833)









Leonard M, Local Anesthesia Volume and Success Rates, JADA Vol. 126(833)



Latency time

The Influence of SOLUTION pH

Primarily due to concentration of **HCI** the LA molecules are dissolved in.

Also proportional to **vasoconstrictor concentration** and the antioxidant, NaHSO₃



The Influence of SOLUTION pH

| generic name | epinephrine | рН |
|----------------|-------------|------|
| 3% mepivacaine | | ~5.4 |
| 4% prilocaine | | ~5.4 |
| 4% articaine | 1:200,000 | ~4.9 |
| 4% prilocaine | 1:200,000 | ~4.9 |
| 2% lidocaine | 1:100,000 | ~4.3 |
| 4% articaine | 1:100,000 | ~4.3 |
| 2% lidocaine | 1: 50,000 | ~3.9 |



Local anesthetic **ages** on the shelf pH goes ♥ i.e. it becomes more acidic **Stings** more

WARNING:

Do not bend, break or stress needles. Serious injuries to you and/or your patient can occur

Septodont Inc. Box Warning Label

Conventional Inferior Alveolar Block



Add and/or administer a true mandibular block

WARNING

Do not bend, break or stress needles. Serious injuries to you and/or your patient can occur

Septodont Inc. Box Warning Label

Akinosi

Gow-Gates

Prognathic Mandible

Foramen "moves" higher and deeper 0



Bisection Injectiondeeper after anterior bone growth

The relative position of the mandibular foramen will vary with the width of the ascending ramus, as shown by the arrows.





Lingual n \rightarrow

Parotid gland which contains branches of facial nerve

Medial pterygoid muscle Inferior dental nerve and artery

23

Can you contact the ramus?







Inferior dental block. Position of syringe in the adult (A) and in the child (B).



Foramen Ovale to mandibular sulcus ADULT



Intranasal Local Anesthesia

The Future of Pain Control in Dentistry?

FDA has now approved: NASAL SPRAY DENTAL ANESTHETIC



13

St. Renatus, LLC July 20, 2016

What is it?

13

- Intranasal Spray of 3% tetracaine,
- An ester formally marketed as 4% Ravocaine[®]
- With 0.05% oxymetazoline which is an α - adrenergic agonist



Utilizes the BD ACCUSPRAY® technology currently delivered with the Flumist® nasal product

Produces regional anesthesia for restorative procedures on teeth # 4-13 and A-J in patients weighing over 88 lbs



St. Renatus, LLC 2016





St. Renatus, LLC 2016



Articaine

PANACEA or PROBLEM?





A statistically significant scientific study demonstrated that:

4% articaine 1:100K performed more efficaciously than

2% lidocaine 1:100K in controlled clinical administrations.

Kanaa, MD et al, J.Endod 32:296-298,2006

Articaine solutions had a probability of achieving anesthetic success superior to lidocaine when analyzing infiltration.

Not as pronounced but still statistically significant, articaine performed superiorly for blocks too.

Articaine Brands: "100" / "200" epinephrine



Septocaine[®] Orabloc[®] Articadent[®] Zorcaine[®]

Articaine Chemistry – Sulfur Atom

- The sulfur atom forming the highly lipid soluble thiophene ring is non-reactive.
- There is NO cross allergenicity (Ag-Ab) interaction for a patient allergic to "sulfas" or "sodium or potassium metabisulfites"
Articaine



Structural formula and physical - chemical data for articaine



Although classified as an amide local anesthetic, the **articaine molecule** is 90% inactivated by plasma *cholin<u>ester</u>ases* and only 10% by *hepatic enzymes*.

Articaine – Metabolite? Safety?

The good news is:

- The metabolite from the ester linkage inactivation is NOT paraamino benzoic acid (PABA), a known allergen.
- The *FAST action* results in a short
 ¹/₂ life (27 minutes). This represents a systemic safety phenomenon.



These authors could not find a single mortality linked to articaine, in any age group, in it's years of dental administration in Europe, Canada and currently the U.S.A.

Hawkins JM, Moore PA, Local Anesthesia: Advances in Agents and Techniques,

Dent Clin N Am 46 2002 719-73

- The product has been available in Germany and France since 1976 and has ~90% of the market, in Canada since 1983 with ~35%, in the United States since 2000, also with ~35%,
- The authors expected to find ADR reports of post-op sequellae such as lingual nerve and/or inferior alveolar nerve paresthesia.

Hawkins JM, Moore PA, Local Anesthesia: Advances in Agents and Techniques,

Dent Clin N Am 46 2002 719-732

Articaine - Search Results - ADR's

This was **NOT** the case, implying that they are:

- Not being reported
- Not occurring
- Accepted as an occasional event in dentistry
- No lawyers in Europe!

Hawkins JM, Moore PA

Paresthesia Research is Unavailable

Is a 4% solution neurotoxic?





There is <u>no</u> scientific or research based data to conclude that

4% prilocaine or4% articaine

is directly causative of dental paresthesia and/or hypesthesia

...HOWEVER...

Paresthesia Product Profile

| | 1973-1993 | 1993 Only | |
|-------------|----------------|--------------|----------------|
| Anesthetic | Incidence %(#) | # Cartridges | Incidence %(#) |
| Articaine | 33.6 (50) | 4,398,970 | 71.4 (10) |
| Prilocaine | 28.9 (43) | 2,353,615 | 28.6 (4) |
| Lidocaine | 3.4 (5) | 3,062,613 | 0 |
| Mepivacaine | 2.7 (4) | 1,569,037 | 0 |
| Bupivacaine | 0 | 241,679 | 0 |
| Unknown | 31.5 (41) | | 0 |

143 Non-Surgical Paresthesia Tongue (92), Lip (42), Both (9)

Haas DA, Lennon D. JCan Dent Assoc 1995;61(4):319-30

"All local anesthetics can produce toxicity to nerves **if** they achieve sufficiently high intraneural **concentrations**.

The concentrations of formulated local anesthetic solutions are neurotoxic per se and that their **dilution**, in situ or in tissue, is **essential** for safe use."

Miller's 7th Edition, 2009

Use articaine for IAN only when others fail!

Becker, DE: Modular Curriculum in Conscious Sedation Manual, 2011



Effects of Lidocaine and Articaine on Neuronal Survival and Recovery

Survey and Anecdotal Reports, 1983 - present

Given that there are reports, although infrequent, of neurotoxity of 4% articaine, this study was designed to compare the neurotoxicity and functional impairment of these two formulations by screening cultured, neural SH-SY5Y cells



Results



4% articaine had no effect on the survival of neural SH-SY5Y cells

Conclusion



4% articaine does not damage neural cells more than 2% lidocaine

This study concludes that articaine is no more neurotoxic, at least in the in vitro setting

Future Overview

THINK of what this could mean

In this in vitro study, since 4% articaine does not damage neural cells and therefore is no more neurotoxic than 2% lidocaine could one

1. Conclude to no longer subject articaine to suggestions that it not be used for IAN and lingual blocks?

2. Reverse the legal settlements involving compensation for paresthesias, at least when the paresthesia is associated with articaine?

THE JURY is STILL OUT.

Future Overview

THINK of what this could mean

In this in vitro study, since 4% articaine does not damage neural cells and therefore is no more neurotoxic than 2% lidocaine could one, furthermore

3. Dismiss the validity of paresthesia <u>survey</u> results?

4. Receive a new product insert which would <u>not</u> need to warn the dentist against using articaine for traditional blocks?

THIS STUDY HAS NOT as YET BEEN PRESENTED at DEPOSITION or in COURT, TO MY KNOWLEDGE

- Don't use it for IAN / lingual nerve blocks.
- Do higher Gow-Gates blocks, where V3 is huge?
- Use selectively Patient selection? History of failure? Desperation? Consent?
- Mix, match, dilute with 3% mepivacaine plain pH 5.4 (Scandanest[®], Carbocaine[®]), administered prior to 4% articaine – pH 4.3 cartridge

Speaker suggests do NOT use on lawyers, news anchor women, any media, family, alleged friends OR at 4:00 PM Thursday OR Friday afternoons.

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