

St. Renatus' Nasal Mist Technology Highlighted in Barcelona, Spain at IADR

St. Renatus' nasal mist technology sparked the interest of many at the 88th annual IADR (International Association for Dental Research) General Session Exhibition July 14-17, 2010 in Barcelona, Spain.

The event took place at the Centre Convencions Internacional Barcelona (CCIB) and brought together members of the IADR's European Region, British, Continental European, Irish, Israeli and Scandinavian Divisions.

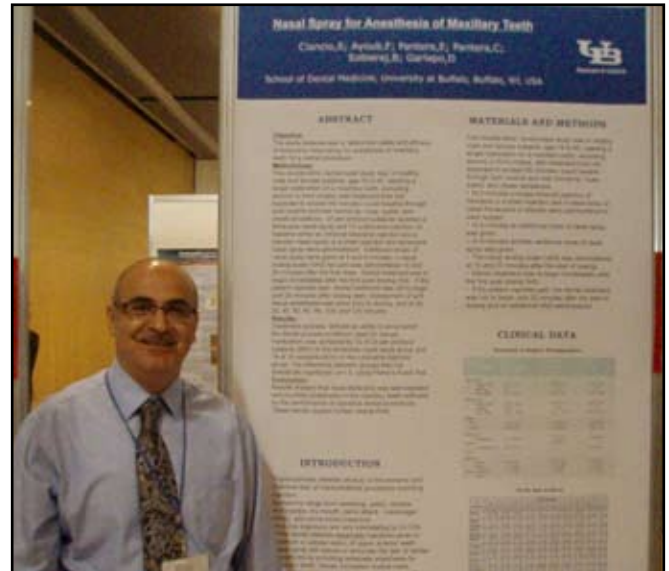
The IADR hosts this events every year in order to accomplish its mission to:

- Advance research and increase knowledge for the improvement of oral health worldwide.
- Support and represent the oral health research community.
- Facilitate the communication and application of research findings.

Source: www.dentalresearch.org.

Dr. Fadi Ayoub, (a full-time Assistant Professor in the restorative department at the University at Buffalo School of Dental Medicine in New York), and other colleagues, including Sebastian Ciancio, Eugene Pantera, Carole Pantera, Benita Sobieraj and Davis Garlapo helped create the research poster titled "Nasal Spray for Anesthesia of Maxillary Teeth." The poster described the objective of the new technology, the process and results from clinical trials, and conclusions to the research.

According to Dr. Ayoub, "the meeting went



Dr. Fadi Ayoub presented a research poster on St. Renatus nasal mist technology at the IADR (International Association for Dental Research) General Session and Exhibition July 14-17 in Barcelona, Spain.

really well and there was a lot of interest in the nasal spray." Dr. Ayoub said most of the questions were related to pediatrics (use in children). He said the Scandinavian dentists and researchers were especially interested in how the nasal mist would affect children, because in their countries the government provides dental care for all school children from preschool through high school.

St. Renatus will continue presenting its technology at conferences, events and for interested groups of dentists, investors and others.

Please see following page to view the full research poster that was presented.

Nasal Spray for Anesthesia of Maxillary Teeth

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Abstract # 133415

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ABSTRACT

Objective:

The study purpose was to determine safety and efficacy of tetracaine nasal spray for anesthesia of maxillary teeth for a dental procedure.

Methodology:

This double-blind, randomized study was in healthy male and female subjects, age 18 to 65, needing a single restoration on a maxillary tooth, excluding second or third molars, with treatment time not expected to exceed 60 minutes; could breathe through both nostrils and had normal lip, nose, eyelid, and cheek sensations. 25 per protocol subjects received a tetracaine nasal spray and 15 a lidocaine injection. At baseline either an intraoral lidocaine injection and a placebo nasal spray or a sham injection and tetracaine nasal spray were administered. Additional doses of nasal spray were given at 4 and 8 minutes. A visual analog scale (VAS) for pain was administered 15 and 20 minutes after the first dose. Dental treatment was to begin immediately after the first post-dosing VAS. If the patient reported pain, dental treatment was not to begin until 20 minutes after dosing start. Assessment of soft tissue anesthesia was done prior to dosing, and at 20, 30, 40, 50, 60, 80, 100, and 120 minutes.

Results:

Treatment success, defined as ability to accomplish the dental procedure without need for rescue medication, was achieved by 22 of 25 per protocol subjects (88%) in the tetracaine nasal spray group and 14 of 15 subjects (93%) in the Lidocaine Injection group. The difference between groups was not statistically significant, $p=1.0$, using Fisher's Exact Test.

Conclusion:

Results showed that nasal tetracaine was well tolerated and provided anesthesia of the maxillary teeth sufficient for the performance of operative dental procedures. These results support further clinical trials.

MATERIALS AND METHODS

This double-blind, randomized study was in healthy male and female subjects, age 18 to 65, needing a single restoration on a maxillary tooth, excluding second or third molars, with treatment time not expected to exceed 60 minutes; could breathe through both nostrils and had normal lip, nose, eyelid, and cheek sensations.

- At 0 minutes a single intraoral injection of lidocaine or a sham injection and a nasal spray of nasal Kovacaine or placebo were administered to each subject.
- At 4 minutes an additional dose of nasal spray was given
- At 8 minutes another additional dose of nasal spray was given
- The visual analog scale (VAS) was administered at 15 and 20 minutes after the start of dosing.
- Dental treatment was to begin immediately after the first post-dosing VAS.
- If the patient reported pain, the dental treatment was not to begin until 20 minutes after the start of dosing and an additional VAS administered.

CLINICAL DATA

Summary of Subject Demographics

Variable	Nasal Kovacaine (N = 30)	Lidocaine Injection (N = 15)	Total (N = 45)
Age, years			
Mean \pm SD	38.6 \pm 12.8	40.8 \pm 15.3	39.3 \pm 13.6
Median	41.1	42.3	41.9
Min - Max	21.4 - 58.9	19.6 - 65.9	19.6 - 65.9
Weight, lbs			
Mean \pm SD	178.3 \pm 42.8	187.8 \pm 42.9	181.5 \pm 42.6
Median	168.8	185.3	175.0
Min - Max	105.0 - 275.0	115.2 - 270.4	105.0 - 275.0
Gender, N			
Male	14 (46.7%)	12 (80.0%)	26 (57.8%)
Female	16 (53.3%)	3 (20.0%)	19 (42.2%)
Ethnicity, N			
Hispanic or Latino	2 (6.7%)	0 (0.0%)	2 (4.4%)
Not Hispanic or Latino	28 (93.3%)	15 (100%)	43 (95.6%)
Race, N			
White	27 (90.0%)	12 (80.0%)	39 (86.7%)
Black or African American	1 (3.3%)	1 (6.7%)	2 (4.4%)
Asian	2 (6.7%)	2 (13.3%)	4 (8.9%)

INTRODUCTION

Trypanophobia (Needle phobia) is the extreme and irrational fear of medical/dental procedure involving injection.

Symptoms range from sweating, pallor, nausea, tachycardia, dry mouth, panic attack (vasovagal reflex), and some times Insomnia.

Intra oral injections are very intimidating to 10-15% of the dental patients especially injections given in vestibule or palatal region of upper anterior teeth. Nasal spray will reduce or eliminate the fear of dental procedures by providing adequate anesthesia for maxillary teeth, hence, increased routine visits, better oral and systemic health, and increased office productivity.



OBJECTIVE

The purpose of this study was to determine the safety and efficacy of Kovacaine for anesthesia of the maxillary teeth for dental procedures.

Primary Objective: To determine if Kovacaine nasal spray provided anesthesia of the maxillary teeth sufficient for the performance of dental procedures.

Secondary Objectives: To determine if Kovacaine nasal spray provided anesthesia of soft tissue, and to evaluate the safety and tolerability of Kovacaine nasal spray and sham injection as compared to sham nasal spray and 2% lidocaine hydrochloride with 1:100,000 epinephrine submucosal injection and as determined by changes in vital signs and reports of side effects and adverse events (AEs).

Teeth and surfaces

by Surface	Tooth Number													
	1R	1L	2R	2L	3R	3L	4R	4L	5R	5L	6R	6L	7R	7L
Distal	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Lingual	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Distal	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Occlusal	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Facial	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Lingual	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mesial	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mesial	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Occlusal	0	0	0	0	0	0	0	0	0	0	0	0	0	0

RESULTS

Treatment success, defined as ability to accomplish the dental procedure without need for rescue medication, was achieved by 22 of 25 per protocol subjects (88%) in the tetracaine nasal spray group and 14 of 15 subjects (93%) in the Lidocaine Injection group. The difference between groups was not statistically significant, $p=1.0$, using Fisher's Exact Test.

Duration of Soft Tissue Anesthesia

Site	Nasal Kovacaine (N = 30)	Lidocaine Injection (N = 15)
Site 1, N	18	13
Mean \pm SD	21.1 \pm 16.9	34.2 \pm 21.0
Min - Max	5 - 65	5 - 85
Site 2, N	9	7
Mean \pm SD	16.1 \pm 16.9	32.1 \pm 8.9
Min - Max	5 - 45	25 - 35
Site 3, N	22	4
Mean \pm SD	31.8 \pm 19.9	25.0 \pm 18.3
Min - Max	5 - 65	4 - 45
Site 4, N	20	7
Mean \pm SD	31.5 \pm 24.1	29.3 \pm 27.6
Min - Max	5 - 85	5 - 85

CONCLUSIONS

The results of this study showed that Nasal Kovacaine was well tolerated and provided anesthesia of the maxillary teeth and soft tissue sufficient for the performance of operative dental procedures. These results support the conduct further clinical trials.

ACKNOWLEDGEMENT

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