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"Botulin Toxin Injection for Management of

Temporomandibular Joint Clicking"

Class Section: E601

April 23<sup>rd</sup>, 2015

Part IV- Final

#### Angela Enache

#### 1. When was the work published?

This research paper was published on February 18<sup>th</sup>, 2013 in the International Journal of Oral and Maxillofacial Surgery. It was also made available online on March 26<sup>th</sup>, 2013.

#### 2. What are the main points of the article? Write a 150-200 word summary of the article that accurately conveys the content of the article.

The research study by A.S. Emara et al, was made to further analyze the effects of the Botulin Toxin-A on patients who have reported clicking of the temporomandibular joint. Six patients were tested and confirmed as having the clicking with NO pain. In total, six patients and a total of eleven joints were subjected to the BTX-A injections. As they explain in the study, there is a relationship between the lateral pyterygoid muscle and "anterior disk displacement with reduction (ADDR)" where atypical movements between the two, cause the clicking. Because the Botulin Toxin-A is approved for use on humans, its effects on paralyzing the "hyperactive" muscle would cause a significant reduction of the click for the approximate four months that the manufacturers describe. Magnetic Resonance images (MRI) of the patients' anterior disk were taken before and after the injections and ultimately verified that the BTX-A injections had in fact affected the joints in an effective way. Through the use of different statistical analysis programs such as SPSS and ANOVA, the researchers put together the evidence and came to the conclusion that the direct relationship between the lateral pyterygoid muscle and the anterior disc of the TMJ and the temporomandibular diseases that can later on evolve, can be reduced with BTX-A injections.

# 3. Does the work meet the standards to be considered an appropriate academic/scholarly source?

Yes. This research paper is a peer-reviewed research paper published in the International Journal of Oral and Maxillofacial Surgery. The International Journal of Oral and Maxillofacial Surgery is one of the "leading journals on oral and maxillofacial surgery in the world". It is also affiliated with the "International Association of Oral and Maxillofacial Surgeons". Aside from the qualifications of the authors of this research, they have also received partial funding by the Faculty of Oral and Dental Medicine, Cairo University. To make sure that they have taken the appropriate and ethical steps in this research, they received approval from the Ethics Committee of the Faculty of Oral and Dental Medicine of Cairo University.

# 4. Are the qualifications of the author(s) appropriate for an academic article? Briefly describe the authors' qualifications.

Yes, the qualifications of the authors are appropriate for an academic article. <u>Dr. Aala</u> <u>Shoukry Emara</u> has a M.Sc. and BDS and is an assistant lecturer of oral and maxillofacial surgery in the Oral and Maxillofacial Surgery Department of Cairo University. He is also a faculty member of Oral and Dental Medicine of Cairo University in Cairo, Egypt. He has also co-authored in other publications found in the International Journal of Oral & Maxillofacial Surgery. <u>Dr. Mohammed Ibrahim El-Faramawey</u> has a PhD, MS, & BDS and is also a part of the Oral and Maxillofacial Surgery Department as well as a faculty member of Oral and Dental Medicine of Cairo University. Dr. El-Faramawey is also affiliated with Lady Hardinge Medical College in New Delhi, India. <u>Dr. Maha</u> <u>Mohammed Hakam</u> is a PhD professor and member of the Oral and Maxillofacial Surgery Department of Cairo University. Dr. Hakam has been co-author in other scholarly publications and has also made other research publications with Dr. ElFaramawey. <u>Dr. Mohamed A. Hassan</u>, has an MD and is an associate professor in the Radiodiagnosis Department and Faculty of Medicine of Cairo University.

#### 5. Is the purpose clearly stated? Restate the purpose of the paper in your own words.

Yes the purpose is clearly stated. With the use of the Botulinum Toxin-A, clicking of the temporomandibular joint would cease for the recommended time of approximately four months. The relationship between the lateral pyterygoid muscle and the anterior disk of the temporomandibular joint allows for the injections to be successful in ceasing the click that patient so often report, without pain.

# 6. Is the experimental design clearly described? Describe the design in your own words.

Yes the experimental design is clearly described. This experiment was a cohort study where six patients were chosen to undergo Botulinum Toxin-A injections to reduce the "clicking" sound that is shown to be related to the lateral pyterygoid muscle and Anterior Disk Displacement Reduction (ADDR) of the temporomandibular joint. The research indicated that effects of the BTX-A injections would be effective for a period of approximately four months, the recommended time made by the manufacturers. All, except for one patient, were similar in that they experienced clicking bilaterally with no pain. This was confirmed with the use of Magnetic Resonance images to verify that the click was associated with the ADDR.

#### 7. Have the possible influences on the findings been identified and controls instituted? Describe and evaluate the use of controls and possible influences (spurious variables).

Yes. The researchers identified factors that could affect the results such as eliminating patients from the study who could have neuromuscular disorders as well as musculoskeletal disorders. There are other methods known for improving the way muscles work such as myofascial therapy, however, these were not mentioned. In that aspect, the authors did not specify whether or not other controls were imposed that could affect the results of the study. Neither did they explain if there were confounders such as habits the patients might have had.

#### 8. Has the sample been appropriately selected (if applicable)? Describe the sample used in the study, and evaluate its appropriateness.

No, the sample was not appropriately selected. Details on their age and the evidence that these patients did report the clicking with no pain were specific and appropriate to the purpose of the study. Unfortunately, the authors failed to differentiate between both genders and their use of only six patients was insufficient. In order for a sample to be a generalization representation, there should be a minimum of approximately 26-30 subjects. The sample was not randomized as these patients were all from the same outpatient clinic and the number of joints used to experiment with the BTX-A injections were inconsistent and uneven (eleven out of the twelve joints were used). Of these six patients, four joints had a reciprocal click while the rest only had a single opening click. Although there was said difference, a one-way analysis of variance (ANOVA) "was used to compare variables within the studied group of patients".

# 9. Has the reliability and validity of the article been assessed? Evaluate, and state the test/diagnosis results.

The validity of this research, with respect to its purpose and the proposed hypothesis was assessed and proven to be of great significance. Although this experiment did not necessarily need examiners to rate the patients' progress, there was no mention of training needed in order to reduce any intra-examiner discrepancies. The methods and materials used were described in a way that would allow for the researchers who did the injections and other materials to yield results that correspond with the experiment. The reliability of the experiment was also assessed and also of significance, where the study can be replicated. The authors also mention that they encourage other researchers to replicate their study. The results yielded the conclusion that the hyperactivity of the lateral pyterygoid muscle is responsible for the "click" with no pain reported. The use of 35 U of BTX-A, compared to other studies that used a range of 40-60 U, showed positive results with less seepage of the material to adjacent areas, including less discomfort for the patients. The maximal inter-incisal opening (MIO) preoperatively dropped from 41.55 mm to 22.64 mm in just the first week, with another significant drop to 11.00 mm in the second week. At the end of the fourth month, it had reached 17.27mm. The researchers used a t-test to show the pre-and post-operative measures of point A (anterior point of the disk) and point B (posterior point of the disk). They showed the mean differences to be 0.62 and 0.83, respectively. This, and the use of SPSS (version 15), one-way analysis of variance (ANOVA) to compare variables within the group of patients, and a post hoc test to identify the differences if the ANOVA tested positive, were completed to produce the statistical analysis. The standard deviation was 0.27 for point A and 0.35 with a p-value of 0.001 (a one in one thousand chance of falsely concluding the effects of BTX-A injections in the LP on the anterior disk of the temporomandibular joint). The BTX-A

injections were proven to be of worth in aiding patients who report the click with no pain. Furthermore, the researchers responded that at the end of the four month period the LP muscle did not revert back to its hyperactive state, which was essentially due to the benefitting use of the BTX-A injections.

# 10. Is the experimental therapy compared appropriately to the control therapy? Describe and evaluate the use of the control group.

Unfortunately this question does not apply to this study. Because, as mentioned before, this study is prospective (or cohort) study where the researchers used the same group of patients and evaluated them according to the time frame previously mentioned.

#### 11. Is the investigation of sufficient duration? Evaluate, and explain your reasoning.

Yes, the investigation was of sufficient duration in regards to what the researchers had explained their purpose to be. The research purpose was to determine the effects of the BTX-A injections in the lateral pyterygoid muscle for the four months that the injections would be effective. It is mentioned in the literature that there should be a follow-up injection at the end of that period in order to strengthen the effects of the first. It is seen in the results that as the four month mark was approaching, the effects decreased and only one joint needed to receive the follow-up injection.

12. Have the research questions or hypothesis been answered? Restate the research questions and/or hypothesis in your own words, and describe if or how they are answered.

Yes, the research hypothesis was answered. The hypothesis of the study was that the BTX-A injections would decrease or cease the clicking sound. Knowing that there was a significant relationship between the lateral pyterygoid muscle and the anterior disc of the temporomandibular joint along with the clicking, the use of these injections could improve the disc position once the hyperactivity of the muscle would be decreased. The researchers reported that the facts were previously researched and that this study would "further investigate the effect of BTX-A injections in the LP on TMJ clicking based on the theory suggesting that the hyperactivity of the muscle in an etiologic factor of the click".

#### 13. Do the interpretations and conclusion logically follow the experimental finding? Restate the conclusion, and explain if or how they follow the experimental findings.

Yes, the interpretations and conclusion logically follow the experimental findings. The conclusion of the study was that by the use of the BTX-A injections into the lower head of the LP, the clicking with no pain would stop. By using the smaller amount of BTX-A injections, the conclusion can be made that "the LP appears to be responsible for the temporomandibular click" and that this treatment would be a successful option for clicking of the TMJ.

#### 14. Do you agree or disagree with the article and findings? Explain why?

Yes. I agree with the articles and findings. Not only is there enough statistical evidence to support the findings, but there are also images that further prove the conclusions made by the researchers. The MR images take pre- and postoperatively were superimposed to visually explain the changes. The postoperative image shows that the disc position improved and because there is a more "normal" range of movement, the clicking terminated. In fact, this further emphasizes the results of other experiments that the researchers referenced to: the LP muscle is responsible for ADDR (anterior displacement of the articular disc).

# 15. What would you change in the article? Why? Think outside of the box. What would you add or delete.

As far as adding or deleting any information in the article, there is nothing I would change. However, I do believe that the actual process of putting together the sample was not solid. The sample size was too small and although the researchers did suggest other researchers should have a bigger sample size, the patients were sort of "just put together". The sample was not specific enough, for example, to all patients having either a unilateral or bilateral click. There was also no mention as to whether or not the patients had any other forms of therapy in conjunction with the BTX-A injections. The other thing I would have liked to see would have been that the follow-up periods be lengthier, as the researchers reported that there was a change in the muscle. The researchers reported this to be a "deprogramming" of the hyperactivity of the muscle that allowed for the clicking to cease for a longer period of time.