Identification, Treatment, Initial and Long-Term Results of Chronic Muscle Spasm Induced Chronic Pain Treated with the CMECD® Procedure

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Abstract: This article was not intended to be a complete report of a standard clinical trial. It is a report of the outcomes of preliminary data for validation of the CMECD® procedure (Coletti Method of EMG ChemoDenervation) protocol for the treatment of chronic pain resulting from chronic muscle spasm. Methods are here detailed on how to approach the patient with chronic pain, identify the presence of chronic muscle spasm, undertake the treatment protocol and how to perform the follow up process to confirm that chronic pain secondary to chronic muscle spasm was the accurate diagnosis. Furthermore, this article presents the results of a cohort of more than 90 patients treated by the CMECD® procedure regarding location and duration of prior pain, prior treatment strategies, degree of success in resolving pain and duration of relief. Outcome data consisting of patient and staff reporting of specific situations in which the chronic pain treatment was successful has been included to help establish the "believability" of outcome successes and to elucidate the potential life altering effects of successful treatment of chronic pain secondary to chronic muscle spasm. This article will hopefully increase the interest in this treatment protocol and increase the chance that a classical international clinical trial will be undertaken.

Keywords: EMG; muscle; spontaneous electrical activity (SEA); spasm; pain; CMECD® protocol, phenoxybenzamine-lidocaine mixture

1. Introduction

This article is not a complete report of a standard clinical trial. It is a report of the outcomes of preliminary data for validation of the CMECD® procedure (Coletti Method of EMG ChemoDenervation) for the treatment of chronic pain resulting from chronic muscle spasm that was compiled over a 15-year period. [1,2,3,4] Methods are here detailed on how to approach the patient with chronic pain, identify the presence of chronic muscle spasm, undertake the treatment protocol and how to perform the follow up process to confirm that chronic pain secondary to chronic muscle spasm was the accurate diagnosis. Furthermore, the survey results of a cohort of more than 90 patients treated by the CMECD® procedure regarding duration of prior pain, location of pain, prior treatment strategies, degree of success in resolving pain and duration of relief are presented. Outcome data consisting of patient and staff reporting of specific situations in which the chronic pain treatment was successful has been included to help establish the "believability" of outcome successes and to elucidate the potential life altering effects of successful treatment of chronic pain secondary to chronic muscle spasm. This article is intended to demonstrate that chronic pain when resulting from chronic muscle spasm can be treated successfully with long-term results with the use of the CMECD procedure. It will hopefully increase the interest in

this treatment protocol and increase the chance that a classical international clinical trial will be undertaken.

2. Materials and Methods

2.1. Diagnostic and treatment step by step procedural approach.

2.1.1. Patient assessment: Chronic pain presents in a variety of forms. Static constant pain, pain on standing, on movement and pain following a given activity may all be secondary to chronic muscle spasm. Not uncommonly there is no appreciation by the individual that their chronic pain is secondary to a chronic muscle spasm. For example, tennis elbow is almost always secondary to a muscle proximal or distal to the elbow but virtually never recognized by the individual. Piriformis syndrome causes sciatica, but the piriformis spasm is not generally recognized as the source of the pain. Pain in the foot is commonly caused by spasm of muscles in the lower leg especially the anterior muscles. Several good works provide a key to the possible muscle spasm that may be responsible for a given pain. One of which by Clair and Amber Davies is my preferred source and is referenced. [5] Their work follows up on the classic work by Travell and Simons "Myofascial Pain and Dysfunction".

2.1.2. Patient examination: Nearly all muscles in chronic spasm exhibit tenderness on compression and seem incompressible. Deeper muscles, such as lumbar muscles, may require significant pressure to elicit discomfort. Comparison of one side to the other can help distinguish true tenderness versus an excessive compression effort. The individual must be placed in position such that the muscle is not in use during the examination. Chronic spasms are frequently found in the calf muscles and in the forearm muscles without the individual being aware of such and represent an excellent learning tool.

2.1.3. Diagnostic procedure: The simplest of EMG devices can suffice for identifying Spontaneous Electrical Activity (SEA) in a muscle in chronic spasm. The presence of SEA in a muscle placed at rest, in a patient without an underlying neurologic condition, is the identifying signature of chronic muscle spasm. Devices with a screen are more satisfying for feedback but devices with sound alone can be used successfully. The EMG device that was originally used and shown in the images below was a Cadwell 5200A. The videos that were placed on YouTube were with use of an Intronix Myoguide EMG. Sensitivity and loudness settings are generally placed in mid-range. On the Myoguide device, settings of 7 and 7 respectively were used. Needle insertion can be performed with or without a skin-freezing agent for pain prevention. Needle insertion always causes some degree of electrical activity. Occasionally, increased insertional activity is encountered which typically is 1-2 second rapid-fire spike that can almost never be recreated by a second insertion or movement of the needle tip. This increased insertional activity, when present, has been found to correlate with muscle membrane instability in muscle not yet

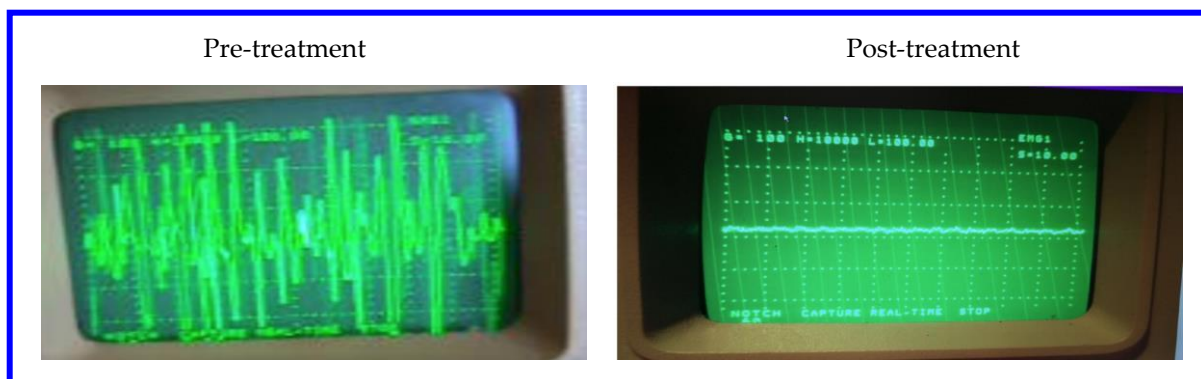
| Pre-treatment | Post-treatment |

in full-blown chronic spasm. Until recently, treatment of those sites was avoided, but good outcomes have resulted in treating selective individuals with that presentation. The classic finding of chronic muscle spasm is highly chaotic, high potential electrical activity in a muscle placed at absolute rest by posture.

Figure 1. Spontaneous Electrical Activity (SEA) in a muscle in chronic spasm (Left panel).   A cocktail of previously prepared phenoxybenzamine 5mg/ml and Dexamethasone 1.5mg/ml is then diluted with equal amounts of Lidocaine 2%. An EMG injecting needle 1.5 to 3 inches is typically used, and very small aliquots of the solution is distributed throughout the muscle until all SEA is abolished (Right panel).

2.1.4. Treatment procedure: A cocktail of previously prepared phenoxybenzamine 5mg/ml and Dexamethasone 1.5mg/ml is then diluted with equal amounts of Lidocaine 2%. An EMG injecting needle 1.5 to 3 inches is typically used, and very small aliquots of the solution is distributed throughout the muscle until all SEA is abolished. A classic finding is that sites as small as a quarter inch/one half centimeter away from an injection site will remain strongly active despite the nearby injection. This is a markedly different approach than trigger point injection or use of botulinum toxin. The needle should be advanced and injections made until all but a small baseline activity remains. Then the needle should be pulled back and directed several degrees away from the initial orientation searching for SEA. Ultimately, a full 360 degree of exploration should be made to assure the muscle is fully treated. Not uncommonly SEA can be found continuing off in an unexpected direction and should be followed often requiring a separate skin penetration. Normally, a maximum of 20ml of the combined solution should be utilized in a single procedure. Phenoxybenzamine is an alpha-blocker and can cause hypotension as a systemic effect for up to 36 hours. Images seen below are typical pre and post treatment EMG findings. A few amateurish treatment videos have been posted online and may be a useful teaching aid. [6,7,8]

2.1.5. Acute Treatment Assessment: If chosen properly, the presenting complaint of pain will be resolved when the individual is asked to recreate it. A good method is to interrupt the procedure after half of the allotted injectate has been used and have the patient stretch or do any movement that would normally elicit the presenting pain. One must be mindful of the phenomena "Hierarchy of Pain" recently reported [9] wherein a subject will immediately sense a second less severe pain as soon as the most significant pain is resolved. Therefore, careful attention to exact sites of pain must be questioned. If the initial site of pain has been resolved and another is then reported, it is perfectly acceptable to perform the EMG examination of that site for treatment. Limitation of the total safe dose of medication used in one sitting may require a subsequent procedure. In the case of tendonopathies, it generally requires 2-3 days for resolution. The pathophysiology of this occurrence is discussed elsewhere. [10]

2.1.6. Follow up Treatment Assessment: It is key to know that while the combined effects of Lidocaine in pain relief and blockade of electrical activity are nearly immediate, the effects of phenoxybenzamine take up to an hour to be effective. Unless the individual is a fast metabolizer of Lidocaine, (often seen in individuals with red hair) there will be a fortuitous overlap of the pain and muscle spasm relief. A follow up visit is therefore strongly recommended to get a full assessment of procedural success. This will be especially important if attempts are made to use an even less concentrated solution of phenoxybenzamine to minimize its irritant effects. This is a consideration for future research.

2.1.7. Timing of Subsequent Treatments: Individual sites that fully resolve SEA almost never require a second injection. Discomfort at the site of injection can last up to one week but usually not more than 2-3 days. Treatment of a second site therefore should be done no sooner than one week from the initial injection.

2.1.8. Post treatment Patient Direction: The longer a muscle has been in chronic spasm, the more injured it has become. Loss of mitochondria with chronic muscle spasm has been reported. [11] Rehabilitation must therefore take into account the degree of muscle atrophy and not require excessive use that would recreate the overuse injury that was responsible for the chronic muscle spasm in the first place.

2.1.9. Risk Profile: Hypotension up to 36 hours and site discomfort represents the primary risk for the use of phenoxybenzamine. Injection procedure deep into lumbar muscles without ultrasound or x-ray guidance has been found to be of minimal risk with no adverse events in at least a hundred of lumbar injections. Deep muscle injections with EMG guidance in the lumbar region can be performed with the knowledge that a needle tip penetration into the peritoneum is unlikely to have a significant adverse effect. Injections in the thoracic and cervical regions require significantly more caution. Respiratory variation of the EMG signal indicates that further penetration of that muscle has a significant risk of lung penetration.

3. Results

3.1. Outcome results

During the development of a new treatment strategy, it is not expected that every individual treated will have dramatic outcome results. In the development of the CMECD® procedure over 30 different muscle groups were treated. [1,12,13,14]

This procedure involves the identification of chronic muscle spasm by the presence of spontaneous activity (SEA) by EMG and the complete resolution of SEA with EMG guided chemodenervation by use of a phenoxybenzamine/lidocaine/dexamethasone mixture. The likelihood of universal positive outcomes in a newly developed procedure is highly statistically unlikely.

As has been previously reported, [9] a population of roughly 100 of the most recent individuals that were treated with the CMECD® procedure was surveyed. Noted below are the results reported in simplest form by the third of the individuals who responded (Table 1).

Of the respondents, 31 (74%) reported years of pain duration (Table 2). Of those, 50% reported complete relief of pain (81% of which reported relief of pain for greater than 3 months) and 27.4% reported moderate relief of pain (44% of which reported pain relief for greater than 3 months) (Tables 3 to 7). The average duration of pain when specified was 5 years and the longest was 15 years (Table 3). A single treated patient, not in this survey, reported near complete pain relief and return of function after 35 years. [5] The full reporting of the survey results, however, were not available at the time of those result being published in abstract form.

The final results are in Tables 1 to 9. A selection this data was presented in a recent article "The Ischemic Model of Chronic Muscle Spasm and Pain". [9]

Table 1.   Questionnaire on Response to Treatment with CMECD® procedure Mailing and Negative Results

Two mailings were made to the most recently treated 92 patients.
Returns of the first mailing of 50 assessment forms: 21
Returns of the second mailing of 70 forms: 21
Total returns: 42
Number stating no pain relief in first mailing: 2, in second mailing: 5

Table 1 indicates the number of patients who responded to fill out an outcome form after two requests. The second request was to encourage patients with no benefit to respond in order to correct the inherent bias of only good outcomes being reported.

Table 2.   Questionnaire on Response to Treatment with CMECD® procedure Positive Results

Number / Percent with significant relief of pain: 35 / 83.3%, complete relief of pain: 22 / 50%, moderate pain relief: 9 / 21.4%, partial pain relief: 4 / 9.5%.

Number / Percent of patients who had prior unsuccessful treatments: 34 / 85%
Number / Percent of patients with prior back surgery: 5 / 12%
Number / Percent of back surgery patients with complete durable relief: 2 / 5%

Table 2 indicates the percentage of patients with significant relief of pain – 83.3% and with complete relief of pain   - 50%.

Table 3.   Questionnaire on Response to Treatment with CMECD® procedure
      Duration of pain prior to treatment and prior treatments

Duration of pain prior to treatment (number / %):
weeks of pain: 1 / 2.4%, months of pain: 9 / 21.4%, years of pain: 32 / 76%

Average number of years when specified: 5.85 years
Maximum number of years when specified: 15 years

Table 3 indicates the duration of chronic pain prior to the procedure. An average duration of 5.85 years was found. In that series the longest was 15 years. It is notable that 76% of patients treated had years of chronic pain. It is notable that 52.4% of the patients had undergone prior epidural injections.

Table 4.   Questionnaire on Response to Treatment with CMECD® procedure
      Duration of pain relief for those patients with pain relief

Less than one week: 4

One week to one month: 5

One to three months: 5

Over three months: 25

Table 4 indicates that of the patients with pain relief 64% had a duration of greater than 3 months taken to indicate that the relief was functionally permanent. Five of the 39 patients had pain relief of one to three months. Patients with relief for that time period are suspect to gone back to full activity too quickly before the treated muscle had fully recovered.

Table 5.   Questionnaire on Response to Treatment with CMECD® procedure
      Referral of family or friends for this procedure

No response: 3 / 7%,

Would not refer: 3 / 7%,

Would possibly refer: 6 / 14%,

Would strongly refer: 16 / 38%

Table 5 indicates the percentage of patients that would refer a family member for this procedure. 74% of patients stated that they would strongly refer or had already referred family for the procedure.

> ### *Table 6.   Questionnaire on Response to Treatment with CMECD® procedure*
> ### *Impact on overall health, wellbeing or ability to function (number / %)*
>
> **No response to question: 2 / 4.8%**
> **No impact: 11 / 26%**
> **Minor impact: 6 / 14%**
> **Major impact: 23 / 55%**
> **Minor or major impact: 29 / 69%.**

Table 6 indicates the effect on health, well being or the ability to function. Notably 55% indicated that the effects of the procedure resulted in a major impact and 69% indicated that the procedure resulted in a minor or major impact.

> ### *Table 7.   Questionnaire on Response to Treatment with CMECD® procedure*
> ### *Decrease in use of pain medications (number / %)*
>
> **No response: 5 / 12%**
>
> **Took no pain meds before: 9 / 21.4%**
>
> **No change in use of pain meds because of no pain relief: 9 / 21.4%**
>
> **Mild decrease in use of pain meds: 4 / 9.5%**
>
> **Moderate decrease in use of pain meds: 5 / 12%,**
>
> **No longer needed pain meds: 18 / 42%**
>
> **Decrease in use or no longer needed pain meds: 27 / 64.3%**

Table 7 indicates the effect of the procedure on reducing or eliminating pain medications. 42% of patients were able to discontinue pain medication and 64.3% were able to discontinue or reduce pain medication following the procedure.

Table 8 indicated the percent of patient who had previous epidural injections who had pain relief following the procedure. 72% had complete or moderate pain relief. Half of which had complete pain relief.

Table 9 indicates the number of treatments received and the number of sites of pain treated. Of note is that two patients that received two treatments that were unsuccessful required subsequent back surgery. 5 of the 42 patients had one procedure with no pain relief. All the remaining patients had pain relief at one or more sites.

Clearly, while the data in Tables 1 to 9 are supportive of a newly developed treatment for chronic pain, they are not sufficient for statistical significance. The procedures that generated the results were from a single solo medical practice not primarily involved pain management and is no longer active. As a result, the data collection is complete and cannot be extended as would be preferential for reporting of an experimental procedure. However, despite the obvious shortcomings of the reported data, there is enough information to demonstrate enough cause and effect that it would be negligent not to report

it to the medical and scientific community. The current need for treatment of pain without the use of opioid drugs necessitates seeking potential treatment options and for that reason such a treatment option is herein presented.

The successful outcomes of those treated and reported upon notwithstanding, the scientific import of this study is the discovery that SEA is both the presenting and responsible agent for chronic muscle spasm and knowledge of which provides potential treatment pathways. Prior reporting of an ischemic model of chronic muscle spasm provides additional potential pathways for treatment. [9]

However, in support the positive outcomes, statistics do not tell the whole story and individual reports of long-term outcomes should be given consideration in valuation of this procedure.

The patient and staff attestations should provide the believability that statistics always seems to

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Table 8. Questionnaire on Response to Treatment with CMECD® procedure
Outcomes in Patients with Previous Alternative Pain Treatment

Of the 18 patients who previously underwent back epidural injections:

Complete and lasting relief: 6

Moderate relief of variable duration: 6

Partial relief: 1

No relief: 5

Thus 12, of the 18 patients who received prior back epidural injections, had complete or moderate pain relief (72%)

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lack. Moreover, the addition of real life circumstances adds another dimension to what otherwise is mere outcome data. Survey results indicate the length of time that relief was sustained but not the life impact of that relief.

Shown below are a few self-reporting examples of what should be considered as valuable as pure digital data in a scientific inquire of correlation and causation.

As may be seen below, some of the patients had a life altering change. Not all patients had dramatic results, but as an experimental treatment is undertaken, that would have been unexpected. With more experience in the suitability of injection sites, the proportion of successful results did improve and would be expected to improve further.

3.2. *Patient and staff attestations*

Table 9. Questionnaire on Response to Treatment with CMECD® procedure
Number of treatments received

One treatment without pain relief: 5

More treatments without pain relief: 2

(Both patients had subsequent back surgery)

3.2.1   July 9, 2012...I am an active runner for many years and have done damage to my hip. The pain was so severe that I had to stop running. I lived with this for a few years and one day you mentioned the treatment you offer. I tried it and it worked! The pain is gone and I am back to running 10 miles per day again.

3.2.2.   July 6, 2012…I have had severe back pain for over 15 years. The injections have relieved this pain 100%. I feel like a new person. I used to wake up with major back pain and could barely get out of bed. Now with your treatments, I can jump out of bed and have zero pain! I feel young and vibrant again…it's simply amazing. For 15 years I could not raise my arm above my head. It forced me to give up golf and working out. Now after the treatments, I go to the gym every day and freely lift weights and exercise without restriction. I am happy to say my handicap is back to 10.

3.2.3.   April 18, 2012…Thank you for being the only doctor to analyze my case. I have been in pain for 12 months after chemo and after you injected me, I was on the dance floor. No pain enjoying the life I was made to have….

3.2.4.   August 17/2012 …I experience extreme back pain. I tried all home remedies to alleviate the pain including but not limited to: aspirin, muscle relaxants, heating pads. I went to see Dr. Coletti on 2/8/12. Dr. Coletti proceeded to give me injections to the painful areas. These injections completely cure the pain and it currently has not returned.

3.2.5.   June 20, 2012…(hospital CEO) My pain is gone at the injection site. I continue to have numbness in my toes, but I am able to wake up in the morning without any stiffness at all, which is really wonderful. Also, I played golf yesterday and usually when I have finished my back will tighten up and I will need to stretch out before doing anything else…not the case though…I feel great.

3.2.6.   April 27, 2015…For the past 15 years I have been suffering from extreme neck and back pain with tremendous headaches. All the doctors, which have been many, have said the conditions were cause of arthritis and that nothing could be done….On April 8, 2015 I received 4 injections in my neck area and on April 23, 2015 one injection. These injections stopped the chronic muscle spasms in my neck and upper back, which resulted in no more neck pain or headaches. After 15 years of suffering this treatment was like a miracle…..

3.2.7.   August 21, 2016…Thank you for the opportunity to share my experience and significant life changing results that I have experienced from your work. As you know, I had tried many methods of pain relief for my lower back pain. This pain prevented me from walking even a quarter of a block. I was unable to enjoy basic activities such as walking my dog, strolling in the evening on the beach, and even walking around the hospital where I was employed as a Chief Operating Officer. As a board-certified Nurse, I am very aware of treatment options available and actually tried numerous methods of pain relief to include injections, massage, acupuncture, and daily multiple dosing of Motrin. None of these gave me anything but some minor relief that was temporary in nature. Your treatment that you provided me on two occasions was successful in eliminating all of my lower back pain. I no long am in need of any other type of treatment or even intermittent relief from medications. I can't thank you enough for what you have done for me. (Note: as of January 2022 there was no recurrence of back pain)

3.2.8.   On November 16, 2015 I walked into Dr. Coletti's office with extreme pain in both legs, in the hamstring area. After the injections I walked out with no pain. It is now August 23, 2016 and I have not experienced the pain since the injection.

3.2.9.   March 2016, Staff note: I had the pleasure of working with Dr. Coletti and seeing firsthand the miracles that walked out of our office after the injections. We had patients walk in with a cane or walker and leave with the cane over their shoulder or someone taking their walker out for them. The greatest was hearing the feedback of how positive the long-term affect was and best of all no more pain meds. The success rate was high. Seeing these patients struggle to get out of their chairs and walk down the hallway and walk out a different person and pain free was amazing. Dr. Coletti has created miracles here for patients who had given up hope and he was their last stop.

4. Discussion

The key feature as noted in this survey is that, except as noted above and in the tables, patients were given only a single treatment that had long lasting result. A single practitioner could generally perform patient evaluation and treatment including history taking, physical exam, explanation of the procedure, obtaining consent, injection of the discovered site of chronic spasm based upon EMG evaluation and post treatment evaluation within a one-hour patient office visit.

Additional treatments were only given to treat additional sites. Repeat injections to a given site were rare and only with a subsequent repeat overuse injury at months to years following the initial treatment. Diagnostic tools in the search for a cause of chronic pain potentially caused by chronic muscle spasm consists of both clinical and technical elements.

These include identification of palpable spasm and tenderness on physical examination and the finding of SEA on EMG of the muscle. Used together these are good prospective tools in this endeavor.

Numeric outcome data and personal reporting play an important role in the acceptance of any newly developed treatment that has the potential to positively impact on an individual's health and function.

In the situation where the data set is limited, statistical evaluation for retrospective diagnosis and putative correlation of chronic pain and chronic muscle spasm is limited. In evaluating the proposed causation of chronic pain from chronic muscle spasm, self-reporting by the subjects provides a deeper understanding of a positive outcome and its impact on wellness. Confirmation of individual outcomes in a self reporting format can provide the necessary "proof" of the etiology of the presenting complaint of chronic pain as resulted from chronic muscle spasm.

5. Conclusions

This article has sought to present adequate information for understanding and subsequently undertaking use of the CMECD® procedure to treat patients with chronic pain caused by chronic muscle spasm. Additional technical information can be obtained on the physician teaching website, CMECD.info and will be available in the soon to be released book "Chronic Muscle Spasm and Pain - Discoveries in the Etiology, Identification and Treatment of Chronic Muscle Spasm and Resultant Chronic Pain" by this author. In conclusion, the treatment of chronic pain caused by chronic muscle spasm can successfully be treated with long lasting results with use of the CMECD® procedure. With this information provided in this article, the online sources and ultimately the upcoming book, it is hoped that a classical international clinical trial could be designed and implemented.

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