PROTOCOL TITLE: Efficacy of superior laryngeal nerve block for chronic cough
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1.0 Objectives / Specific Aims

AIM: Determine the overall efficacy of superior laryngeal nerve blocks for the treatment of neurogenic chronic cough. This is the primary aim of the study: to test the hypothesis that superior laryngeal nerve blocks are an effective treatment for neurogenic cough based on existing retrospective data. This will be achieved through the design of a prospective, single-blind, randomized clinical trial in which one group of patients will undergo a series of two standard (steroid-lidocaine mixture) injections and the second group will undergo a series of two placebo (saline) injections. By determining if a clinically significant difference exists between the outcomes of the two groups, measured by a dichotomous yes/no response to improvement, the Leicester Cough Questionnaire, and a visual analogue scale for symptom severity. This will provide the answer to the general question of whether or not these injections are clinically effective for patients with neurogenic cough. Furthermore, any adverse reactions will be thoroughly documented. The significance of this specific aim is to confirm the clinical utility of superior laryngeal nerve blocks; if proven effective, this can greatly improve the care of these patients by allowing for an evidence-based treatment option.

Given the focus and timeframe of the proposed project, this one aim to determine overall efficacy is sufficient; however, it could be further subdivided:

Aim 1a: Determine if patients who undergo a series of superior laryngeal nerve blocks report improvement in cough severity and quality of life.

Aim 1b: Determine the placebo effect of superior laryngeal nerve blocks in the treatment of neurogenic chronic cough.

Aim 1c: Determine the average amount of time post-injection at which symptoms return.

Aim 1d: Determine the rate of complications of in-office superior laryngeal nerve blocks.

By confirming the efficacy found in retrospective studies and developing an optimal protocol for these injections, this project overall aims to improve evidence-based treatment options for patients with neurogenic cough. This has the potential to shift the treatment paradigm for this disease process from daily dosing of a neuromodulating medication to local therapy directed at the superior laryngeal nerve. For patients diagnosed with neurogenic cough, the findings of this study could have a significant impact on limiting or eliminating their symptoms and improving quality of life.

2.0 Background

Chronic cough, defined as a cough lasting greater than or equal to 8 weeks, is a common problem with a lifetime prevalence estimated at 7 to 12% in the adult population.[1-2] These symptoms are often quite frustrating and functionally limiting for these individuals, leading to substantial morbidity. In fact, multiple studies have demonstrated a significant decrease in quality of life, particularly within psychosocial domains, due to chronic cough.[3-4] Cough severity varies across patients and is often perceived in terms of the frequency of coughing fits or urges, intensity, and disruptions.[5]

A wide differential diagnosis for chronic cough exists, creating substantial diagnostic and treatment challenges. Chronic cough may be secondary to gastrointestinal reflux, pulmonary disease such as asthma or COPD, smoking, upper airway cough syndrome, and/or medication use (i.e. angiotensin converting enzyme or ACE inhibitors).[1-2,6-8] A significant subset of patients, however, are found to have cough related to a sensory neuropathy, also known as a “neurogenic cough.” In these individuals, there is hypersensitivity of the internal branch of the superior laryngeal nerve, likely a result of post-viral infection, that leads to a decreased threshold for the stimulation of afferent cough receptors.[9] This

diagnosis is often one of exclusion, after the other possible etiologies of cough have been thoroughly evaluated.[10]

Several treatments have been explored for neurogenic cough, including the use of neuromodulating medications (i.e. amitriptyline, gabapentin, pregabalin, baclofen, and tramadol).[10-14] Ryan et al. found that about 67% of patients taking amitriptyline for chronic cough had greater than 50% improvement in symptoms; however, 64% of patients discontinued use of the medication at follow up. Of these patients, 48% discontinued amitriptyline due to its side effects, which include sedation, dry mouth, anxiety, insomnia, weight gain, and dizziness.[11] Similarly, gabapentin and pregabalin have shown some efficacy in the treatment of neurogenic cough, but they are not effective in all patients and there are concerns for systemic medication side effects.[12] Dion et al. have proposed further evaluation of tramadol for neurogenic cough, however, opioid dependence is a significant concern.[13] In addition to neuromodulating medications, suppression (cognitive behavioral) therapy can be a useful adjuvant but is more effective when combined with medical therapy.[15] Lastly, botulinum A injections and injection augmentation have been suggested for chronic cough, but have been found to have limited use in clinical practice.[16,17]

Superior laryngeal nerve (SLN) blocks, which involve a percutaneous injection of lidocaine and steroid, have been widely described in the Anesthesiology literature as a safe and effective anesthetic during awake fiberoptic intubation.[18-20] The literature on superior laryngeal nerve blocks for the treatment of chronic cough is limited, but there are two published retrospective studies supporting the efficacy of in-office SLN injections[20-21] Simpson et al. reported a series of 18 patients who underwent an average of 2.4 SLN blocks with a statistically significant decrease in cough severity index scores from 26.8 to 14.6 following treatment. No significant adverse outcomes were reported.[21] Dhillon similarly showed a statistically significant decrease in post-treatment cough severity index scores following SLN injections in a cohort of 10 patients without any adverse effects.[22]

Recently, we retrospectively reviewed our experience at the Medical University of South Carolina with in-office SLN blocks for the treatment of chronic neurogenic cough and our unpublished data are consistent with the work of Simpson, et al. and Dhillon. We found that within a cohort of 23 patients (4 males, 19 females, average age 63.6 years), 17 (74%) reported improvement with the injections, 2 (9%) reported initial improvement followed by return to baseline, and 4 (17%) did not have any improvement. The average number of SLN blocks performed per patient was 3.8. Of the 23 patients, 13 had recorded pre- and post-treatment Hull Cough Sensitivity Questionnaire scores and changes in scores were significantly improved from an average of 38 to 23 ($p = 0.005$). All patients reported their symptom severity on a scale of 0-10 and there was a significant negative correlation between the number of injections and symptom severity scores with the largest difference following the initial injection (Figure 1). There were no major adverse events, however 4 patients (17%) reported self-limited post-injection globus sensation.

Although the current data support the efficacy and safety of SLN blocks for chronic neurogenic cough, there are no prospective investigations. Questions remain regarding safety and efficacy, particularly the potential for placebo effect, as well as proper medication dosing and timing. Our hypothesis is that superior laryngeal nerve blocks will provide significant improvement in cough severity compared to placebo. By better understanding the efficacy of superior laryngeal nerve blocks in the treatment of chronic cough, the care of patients presenting with this common symptom will be optimized.

3.0 Intervention to be studied (if applicable)

As mentioned above, superior laryngeal nerve (SLN) blocks, which involve a percutaneous injection of lidocaine and steroid, have been widely described in the Anesthesiology literature as a safe and effective anesthetic during awake fiberoptic intubation.[18-20] The literature on superior laryngeal nerve blocks for the treatment of chronic cough is limited, but there are two published retrospective studies supporting the efficacy of in-office SLN injections[20-21] Simpson et al. reported a series of 18 patients who underwent an average of 2.4 SLN blocks with a statistically significant decrease in cough severity index scores from 26.8 to 14.6 following treatment. No significant adverse outcomes were reported.[21] Dhillon similarly

showed a statistically significant decrease in post-treatment cough severity index scores following SLN injections in a cohort of 10 patients without any adverse effects.[22]

Triamcinolone and lidocaine are both FDA approved injectable medications that have been used in peripheral nerve blocks as mentioned above. The proposed dosing of 2 mL of a 1:1 triamcinolone 40mg: 1% lidocaine with 1:200,000 epinephrine for the superior laryngeal nerve blocks in this study is due to standard practice at MUSC. Similar dosing has been used in the studies mentioned above by Simpson et al. and Dhillon.[20-21] Saline will be injected as the placebo substance, which has no active ingredient.

4.0 Study Endpoints (if applicable)

Primary study endpoints include improvement in cough, measured by dichotomous yes/no response to improvement, the Leicester Cough Questionnaire (LCQ), and a visual analogue scale for symptom severity. Due to its validation, the LCQ will be the primary outcome measure. Secondary study endpoints include the complication and side effect rate from the injections.

5.0 Inclusion and Exclusion Criteria/ Study Population

A chart review of all participants will be conducted at the initial visit for basic demographic information and co-morbidities. Inclusion criteria includes a history that is consistent with neurogenic cough (i.e. preceding viral illness, cough triggered by normal laryngeal functions such as voicing or laughing, environmental triggers such as perfume or noxious odors, etc.), exclusion of other well-known etiologies of cough and age ≥ 18 years. As part of the standard of care at our institution, patients are not treated for neurogenic cough until other etiologies of cough are excluded. Therefore, no funding for this study will be used in the evaluation of gastrointestinal reflux disease (GERD), pulmonary disease, or upper airway cough syndrome, as this is done routinely prior to diagnosis of neurogenic cough. All of our patients prior to enrollment in this study will have normal pulmonary function testing performed since their cough started, and a chest x-ray within the past six months. If a patient has known GERD or a history consistent with laryngopharyngeal reflux with a Reflux Symptom Index (RSI) > 13 or Reflux Finding Score (RFS) >11, then the patient will undergo evaluation for GERD including pH testing, EGD, high resolution manometry and/or esophagram. All of this standard of care testing for the evaluation of chronic cough will be done prior to patient enrollment and consent. Exclusion criteria will include patients on ACE inhibitors or Angiotensin II receptor blockers (ARBs), patients with uncontrolled obstructive sleep apnea, current smokers, and current neuromodulating medication use for chronic cough. If a patient presents on a neuromodulating medication, but is weaned off prior to the start of superior laryngeal nerve blocks, they may be included. This scenario may be encountered for those patients in whom a neuromodulating medication was not effective. Former smoking history will be permissible in the absence of pulmonary disease. A list of the inclusion and exclusion criteria are summarized in Table 1, shown below.

Table 1. Inclusion and Exclusion Criteria for Study Enrollment

Inclusion Criteria	Exclusion Criteria
History consistent with neurogenic cough	Current neuromodulating medication use
Exclusion of other etiologies (see exclusion criteria)	Untreated other etiologies of cough
	Current smoker
Age ≥ 18	Current ACE/ARB use
	Abnormal PFTs obtained after cough started
	Uncontrolled OSA
	Abnormal CXR within 6 months
	RSI > 13 or RFS >11
	AND
	Workup positive for GERD (esophagram, 24-hour pH probe, manometry, EGD)

Children will be excluded in this study as they are a vulnerable population and neurogenic cough typically affects older adults.

6.0 Number of Subjects

We will recruit 50 patients. Our institution has several otolaryngologists who routinely treat chronic cough and, within the past year, a single provider performed superior laryngeal nerve blocks on 29 patients, with the majority of the injections occurring within the last 2-3 months. Therefore, we are confident in our ability to recruit 50 patients within 1 year. Assuming a dichotomous outcome of >50% improvement or not, a 70% treatment effect, a 25% possible incidence of improvement in placebo, and an 80% confidence level, we would need 18 patients in each group (total N=36) to power our study.

7.0 Setting

Patients will be recruited and injections will be completed in the ambulatory clinic setting.

8.0 Recruitment Methods

Patients will be seen in ambulatory clinics as part of a standard workup for chronic cough. The research team will also distribute recruitment flyers in common areas of the MUSC campus, particularly in Otolaryngology, Pulmonology and Gastroenterology clinics. Patients will be screened at the initial visit if they meet inclusion criteria or at further visits after additional workup for other sources of cough is completed, patients will be offered participation in the study. The PI and co-investigator will be in the ambulatory clinics to offer participation in the study. Primarily, the principal investigator will discuss risks and benefits of study participation with the eligible subjects using the informed consent form. There will be no additional advertisements; subjects will be recruited within the standard clinical practice of the clinic.

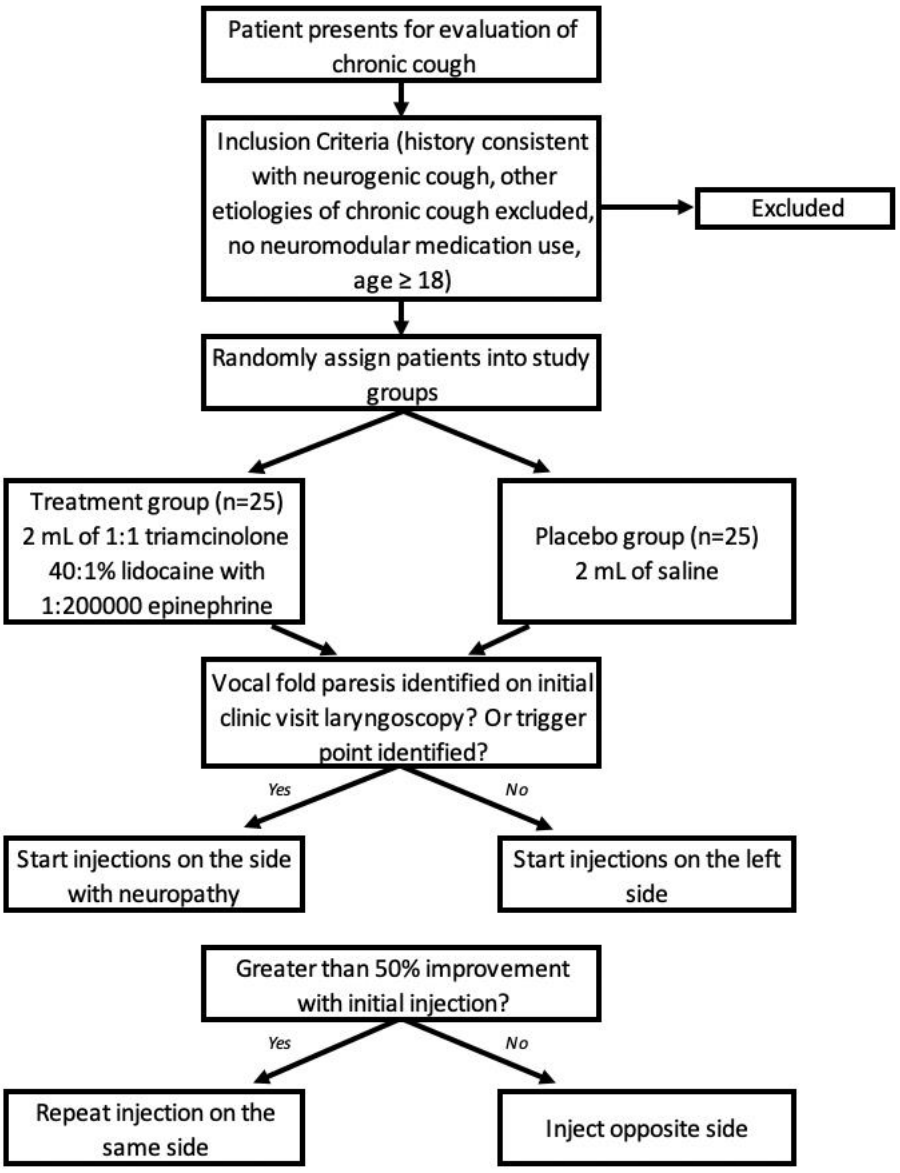
9.0 Consent Process

The principal investigator and qualified research staff will be responsible for obtaining informed consent. These qualified team members will sit with patients and run through the informed consent document that describes the purpose of the study and benefits and risks in non-scientific language. This will take place in the clinic. Consent will only be obtained from the participant. There will be no waiting period available between informing the prospective subject and obtaining the consent, unless the patient requests more time to review the document prior to signing the consent form. Consent will not be completed until exclusion and inclusion criteria met.

10.0 Study Design / Methods

Figure 2 depicts the flow diagram of the study design. Once patients have met inclusion and exclusion criteria (including undergoing all diagnostic testing for other potential causes of chronic cough) and have agreed to study participation, informed consent will be obtained and they will be randomized into two groups: treatment and placebo. This will be achieved using randomly-assorted, secured envelopes containing a card indicating whether the patient will be in the treatment or placebo group. This will be unveiled immediately to the provider administering the first injection, but remain unknown to the subject. There will be 25 “Treatment’ and 25 “Placebo” cards within the 50, individually-secured envelopes. On initial visit, prior to the injection, patients will first undergo nasal laryngoscopy as part of standard of care. If there is any vocal fold weakness seen on scope examination or if there is a unilateral trigger point identified, then the first injection will start on the side of the suspected neuropathy. If there is no evidence of neuropathy on examination, we will start with a left-sided injection. Injections will be standardized to 2 mL of a 1:1 triamcinolone 40mg: 1% lidocaine with 1:200,000 epinephrine. Injection syringe will be brought into room by the physician in an opaque box and placed behind patient so they cannot view the syringe prior to injection. During the injection, a paper “shield” will be held under the patient’s chin by an assistant and they will be asked to close their eyes so that they are not able to view the syringe during injection. This is necessary as steroid possesses a white color as compared to clear saline. The practitioner is not blinded so that proper drawing back on the syringe is not compromised to avoid intravascular or airway injection.

Figure 2. Flow Diagram of Study Design



Injection will be completed near the lateral thyrohyoid membrane by a single experienced laryngologist per previously published methodology utilizing bony, soft tissue and cartilaginous landmarks.[21,22] An illustration of the anatomic target for the injection can be seen in Figure 3. To minimize patient discomfort, lidocaine cream will be applied to the skin prior to injections.

Following injection, patients will be instructed to follow up in a 2- to 3-week time frame; however, we will include all patients in analysis if they follow up within 1-4 weeks. Any follow up outside of that window will lead to removal of the patient's data from the analysis. At follow up, if the patient's cough has improved by greater than or equal to 50% compared to baseline, we will repeat the injection on the same side. If less than 50%, we will move to the other side to perform the injection. Patients will undergo a total of two injections before data collection is complete for analysis. If patients were to experience full resolution of cough (i.e. report 0/10 for cough severity) after the first injection alone, then at that point, their condition would be considered cured and their enrollment in the study will finish. The reason for this is to avoid unnecessary and unindicated injections in patients with resolution of cough.

2 weeks after the second injection, participants will be unblinded. If in the placebo group, they will have the opportunity to complete 2 additional treatment injections (unblinded) under the study protocol. Data will be collected and stored in the same fashion as prior to unblinding.

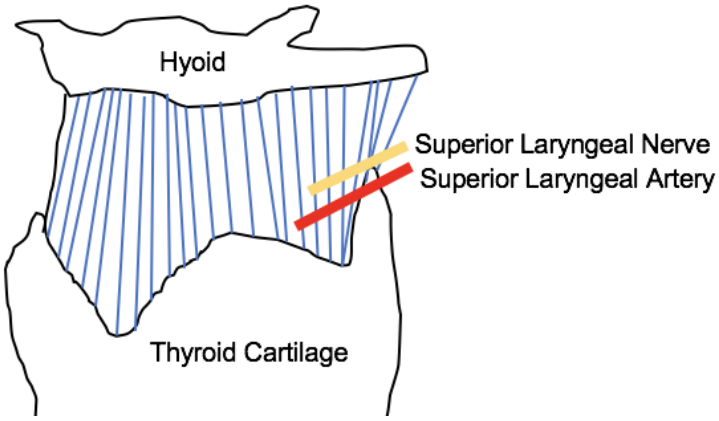
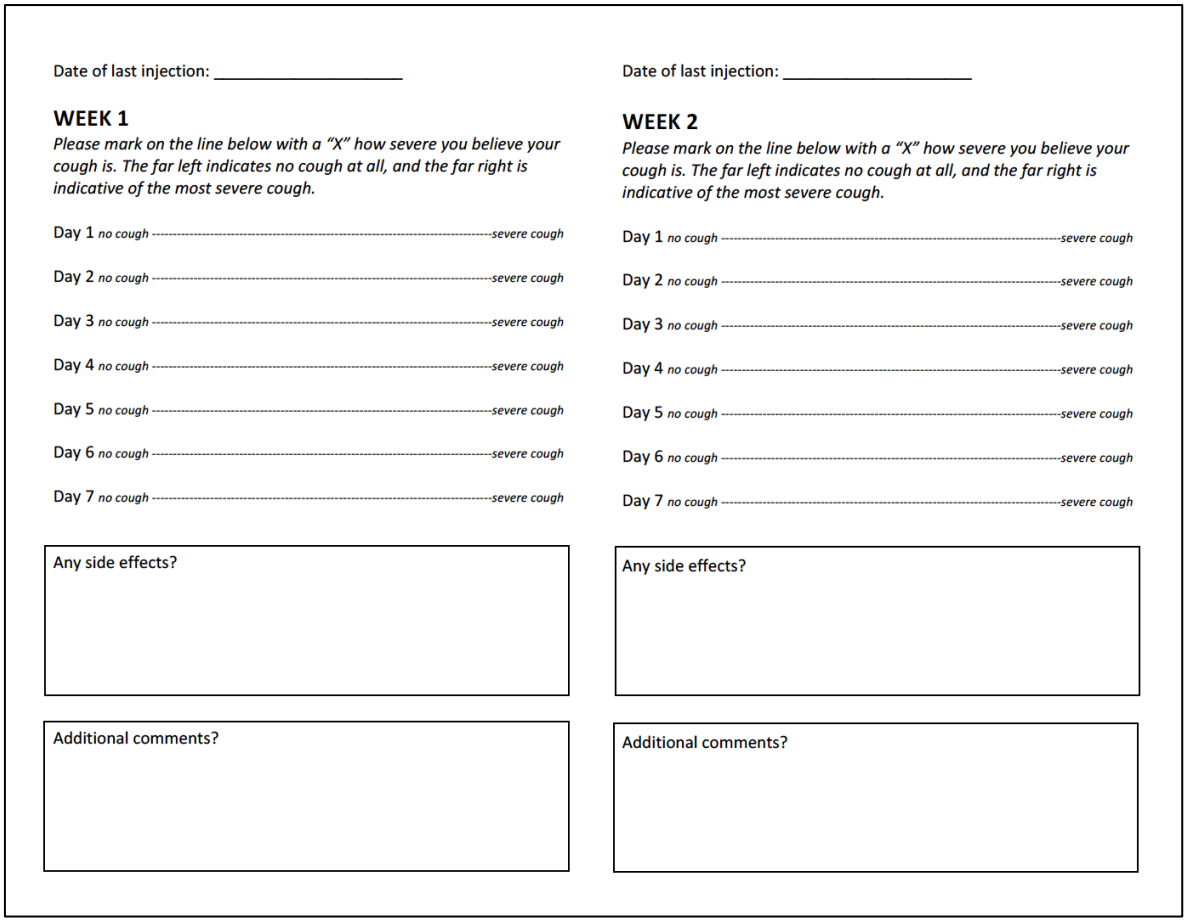


Figure 3. Anatomic Target of Superior Laryngeal Nerve Blocks. During the procedure, the thyroid cartilage, hyoid, and thyrohyoid membrane are palpated as key anatomic landmarks. The target of the injection, the superior laryngeal nerve, pierces the thyrohyoid membrane superior to the superior laryngeal artery. The plunger is drawn back prior to injection to ensure needle tip is not intravascular. Illustration by author.

Patients will be provided a log to track their progress throughout treatment. This will include a visual analogue scale to be completed daily after each injection to document cough severity, as well as opportunities to document any adverse effects or general comments. An example of this log can be seen in Figure 4. At each follow up visit, patients will provide a dichotomous answer (Yes or No) if they experienced improvement in cough and will disclose how long the improvement lasted. They will also fill out the Leicester Cough Questionnaire (LCQ), a validated 19-question quality of life survey for chronic cough.[23] The LCQ will be the study's primary outcome measure. Please see Appendix 1 for a copy of the Leicester Cough Questionnaire. After the last injection, patients will return to the clinic in three months or opt to be contacted via telephone to assess if symptoms have returned.



Date of last injection: _____

WEEK 1

Please mark on the line below with a "X" how severe you believe your cough is. The far left indicates no cough at all, and the far right is indicative of the most severe cough.

Day 1 *no cough* ---------- *severe cough*

Day 2 *no cough* ---------- *severe cough*

Day 3 *no cough* ---------- *severe cough*

Day 4 *no cough* ---------- *severe cough*

Day 5 *no cough* ---------- *severe cough*

Day 6 *no cough* ---------- *severe cough*

Day 7 *no cough* ---------- *severe cough*

Any side effects?

Additional comments?

Date of last injection: _____

WEEK 2

Please mark on the line below with a "X" how severe you believe your cough is. The far left indicates no cough at all, and the far right is indicative of the most severe cough.

Day 1 *no cough* ---------- *severe cough*

Day 2 *no cough* ---------- *severe cough*

Day 3 *no cough* ---------- *severe cough*

Day 4 *no cough* ---------- *severe cough*

Day 5 *no cough* ---------- *severe cough*

Day 6 *no cough* ---------- *severe cough*

Day 7 *no cough* ---------- *severe cough*

Any side effects?

Additional comments?

Figure 4. Patient Symptom Log

11.0 Specimen Collection and Banking (if applicable)

Not applicable.

12.0 Data Management

Descriptional analysis of all demographic data, including sex and age, will be completed. Dichotomous data will be summarized as percentages per group per injection and compared via chi-squared analysis. Changes in Leicester Cough Questionnaire scores, both global and specific domains (physical, psychological and social), will be analyzed via a linear regression model. An independent t-test will then be used to compare both study arms. Regression analysis will also be performed on the data collected from the patient log, specifically the daily visual analogue scale. A ruler will be used to the identify the exact percentage along the scale that represents the patient's cough severity. A comprehensive compilation of side effects reported by the treatment group will be reported as a proportion of the total number of patients in the treatment study arm (n = 25) and compared to the placebo group (n=25). The data collected from the placebo group pre-unblinding will be directly compared to the results achieved from treatment injections offered following unblinding.

Data will not leave MUSC. Patient identifiers (MRN) will be kept coded on a separate, password-protected file stored on a secure drive.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)

The patients will keep a log of all symptoms and concerns throughout the treatment. This will be helpful in determining the side effect rate from injections, but more importantly, provides a way to monitor patient safety throughout the procedure. At minimum these will be reviewed every 4 weeks, but more likely every 2 weeks. Patient's will also be provided with a direct communication line if they have questions or concerns related to the injection.

If any serious adverse events were to occur, these would be immediately reported to the IRB and the study would terminate out of respect for patient safety. Data reviewed include safety data, untoward events, and efficacy data. The primary investigator will review the data.

Participants may withdrawal from study participation at any point if they choose to do so without any influence or coercion.

15.0 Risks to Subjects

While no major adverse effects following SLN blocks for chronic cough have been reported in the current literature or found in our own experience, potential adverse events could include bruising, bleeding, laryngospasm, dysphagia and/or aspiration, swelling or fluctuance, dysphonia, or infection. Minor discomfort and self-limited globus sensation are not unexpected but typically mild. There is a theoretical potentially severe adverse event of intra-arterial injection resulting in blindness or stroke. The physician will always draw back on the syringe prior to injection to ensure that the needle is not intravascular and will perform a slow injection to prevent retrograde flow into the external carotid system to prevent this theoretical event. The study will be monitored by our Institutional Review Board and will be terminated early if any serious adverse reactions were to occur.

16.0 Potential Benefits to Subjects or Others

There is potential benefit for improvement of neurogenic cough, particularly in the group receiving superior laryngeal nerve blocks compared to placebo. Regardless, this study has the potential to benefit many individuals suffer from neurogenic cough by allowing for greater scientific knowledge on the efficacy of superior laryngeal nerve blocks.

17.0 Sharing of Results with Subjects

Results of the study and patient-specific data will be shared with subjects at completion of the study at the completion of the study, at the 3-month follow up.

18.0 Drugs or Devices (if applicable)

Triamcinolone injectable solution and 1% lidocaine with 1:100000 epinephrine injectable solution will be kept in the clinic. Expiration dates will be assess prior to using for injection. Both medications are

approved by the FDA and have been used for superior laryngeal nerve blocks in the literature without serious adverse effects.

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