Cervical medial branch blocks versus trigger point injections with cervical medial branch blocks in patients with concurrent zygapophyseal and myofascial pain

Jason G. Lee, MD
Department of Physical Medicine and Rehabilitation
University of Kentucky
Research Day, 2014
Researchers

• Jason Lee, MD
• Pravardhan Birthi, MD
• Jay Grider, DO, PhD, MBA
Departmental Affiliations

Department of Anesthesiology Interventional Pain Medicine, University of Kentucky

Department of Physical Medicine and Rehabilitation, University of Kentucky
Disclosures

• None
Chronic cervicalgia secondary to cervical facet joint syndrome with associated chronic myofascial pain syndrome is unfortunately a very common disorder and increasingly prevalent disorder.

The prevalence has been described in controlled studies as varying from 39% to 67%.

As we age, or as in patients with degenerative disc disease, the intervertebral discs lose volume and function resulting in increased weight bearing of the zygapophyseal (z) joint from up to 33% normally to approximately 70% in severe cases of degenerative disc disease.
During this process, the well-innervated synovial z joints begin to degenerate resulting in significant back pain with subsequent functional decline in patients around the world.

Cervical facet syndrome is associated with mild-severe shoulder pain, neck pain, headache, suprascapular pain, scapular pain and upper arm pain.
• Myofascial pain syndrome is often associated with facet arthropathy and creates trigger points that are also significant pain generators.

• Bogduk et al. demonstrated the pain referral patterns of each cervical facet joint by injecting hypertonic saline into the cervical facet joints of normal volunteers to characterize the referral pattern of each joint.

• Coincide with myofascial pain and trigger point formation patterns.
Background

• Myofascial pain is local and referred pain that arises from trigger points.

• **Trigger points** are defined as very sensitive areas in skeletal muscle that contain palpable taut bands of muscle which are exquisitely tender to palpation, reproduce the patient’s pain, and often refer pain.

• Found in **85% of patients referred to pain clinics** emphasizing the importance of this study.
Background

- Intra-articular / peri-articular injection into the cervical facet joint region can effectively inactivate upper trapezius myofascial trigger points secondary to the facet lesion
  - Randomized double blind control trial, Tsai et al
- Another recent randomized control trial demonstrated significantly increased cervical range of motion, pain reduction, and decreased incidence of tension headaches with the addition of therapeutic facet joint injections in patients with long standing myofascial pain syndrome with referral pain of cervical facet joint syndrome.
Background

• Medial branch blocks are recommended in the cervical region over intra-articular injections due to greater benefit with less risk to surrounding structures such as the dural sac, epidural space, and vertebral artery.

• These injections are primarily for diagnostic purposes but have also been proven in many studies to be very therapeutic as well.
Background

- Radiofrequency neurotomy is the procedure that is performed following accurate diagnosis with Medial branch blocks and has also been proven in randomized double-blinded control trials to provide statistically significant and longer duration of pain relief.
- One study showed that neurotomy provided more than 50% pain relief for 255 days longer than the placebo group.
- Strong evidence for short-term relief of less than 3 months.
- Moderate evidence for long-term relief of greater than 3 months.
• To our knowledge, no formal research has been done to compare the benefits of cervical vs cervical and myofascial treatments simultaneously.

• The purpose of this study plan is to apply the information learned here toward the development of improved treatments to significantly reduce pain in the future.
Objectives

• The central hypothesis:

• To determine the clinical effectiveness of therapeutic local trigger point injections with or without anesthetic cervical medial branch blocks in managing chronic neck pain of facet joint origin and concurrent myofascial pain.
Study Design

• Randomized double blinded controlled trial
• We will randomize 80 patients with facet joint and myofascial pain to one of the following groups:
  – 1) Trigger point injections
  – 2) Trigger point injections with medial branch blocks
• We will randomize the patients using an experimental-design generator and randomizer program for simple random allocation into equal-sized groups
• Total participation will be approximately 12 weeks
Study Population

- \( \geq 18 \) years of age
- Patients who have failed conservative treatment for 6 weeks
- Patients with clinically diagnosed pain of facet and trigger point origin with or without radiographic evidence
- Pain of \( >4 \) on VAS scale
- Pain episodes must occur at least weekly
- Pain is not secondary to systemic inflammatory arthropathy
  - Pain that requires intermittent or ongoing treatment with narcotics
  - Severe, debilitating, or acute pain primarily originating from sources other than the zygoapophyseal joint or lumbar myofascial pain
- Patients currently on therapy directed toward other mild to moderate pain will be evaluated on a case by case basis for inclusion
Patients with well-controlled mild to moderate pain, such as that associated with degenerative disc disease, disc herniation, or vertebral osteoarthritis will be excluded.

Aspirin for pain relief or for other indications is also acceptable.

Concurrent specified rescue pain medication allowed.

No infection at the intended site of injection.

No allergies to lidocaine, bupivacaine, or steroids.

No medical condition that would preclude study participation.

No zygoapophyseal steroid injection or lumbar dorsal rami RFA procedure within 3 months.
Study Population Cont...

- No cervical radiculopathy on electrodiagnostic examination if applicable
- No history of cervical stenosis on magnetic resonance imaging (MRI) or computed tomography (CT)
- Previous neck trauma from traffic accident or fall to exclude whiplash associated disorders
- Men, women, and minorities will be included in the study provided inclusion criteria are met
- Women of childbearing age will not be excluded from the study, however pregnant women will be
- Non-English speaking subjects will also be excluded
Study Recruitment Methods & Privacy

• Recruitment and initial contact will occur in the clinic setting with patients referred to the clinic.

• Following clinical diagnosis with zygoapophyseal and myofascial pain generators medically appropriate for the treatments provided in this study, recruitment will be discussed with patients who satisfy the criteria for the study population.

• Subjects will then be randomized into one of the two study groups.

• No advertising will be performed for recruitment purposes.
Informed Consent Process

• After randomization, the procedure(s) will be explained to the patient at the initial appointment.
• The formal informed consent will occur prior to the procedure and will include presentation of optional therapies including doing nothing, as well as a detailed description of risks and benefits as listed below.
• Either trained clinic staff or a study doctor will obtain the informed consent.
Research Procedures

- During week 0, initial visit: Subjects will have eligibility confirmed through history and physical exam, complete evaluations and questionnaires.
- During this visit, the subject will receive trigger point injections into one or more of the following muscles: trapezius, splenius capitis or cervicis, levator scapulae, anterior and/or medial scalene, supraspinatus, and infraspinatus with or without medial bundle branch blocks with 0.5cc 1% Lidocaine without epinephrine after randomization.
- Trigger point injections will be performed with 0.25% Lidocaine diluted with sterile 0.9% saline. The subject will receive 3cc in each cervical trigger point.
- Estimated visit length: one day
Research Procedures

• During week 1, 1 week follow up: Subject will return to pain management clinic for follow-up evaluation, questionnaires.

• Subjects will receive trigger point injections as above with or without radiofrequency neurotomy in the bundle branch block group if the blocks were positive.

• Estimated visit length: one day
Research Procedures

• During week 12: Subject will return to the pain management clinic for follow-up evaluation, questionnaires, and pain diary submission for review.

• Directed interim history and physical examination, complete questionnaires about pain including VAS scale and quality of life

• Evaluated at that time by a physician who is unaware of which treatment/s the patient received for double blinded study

• Estimated visit length: one day
Potential Risks

• Reproductive risks: If you are pregnant, or think you may be pregnant, inform the study doctor prior to receiving treatment so that appropriate tests and precautions can be performed. This procedure involves fluoroscopy which can be harmful to a fetus.
Procedure Risks

• Medial branch nerve blocks: Pain during &/or after the procedure, bleeding, bruising, infection, damage to surrounding structures such as bone/cartilage/muscle/ vessels/nerves, allergic reactions which can be life threatening if untreated, heart irregularities, dizziness or lightheadedness, death

• Trigger point injection risks: Pain during &/or after the procedure, bleeding, bruising, infection, damage to surrounding structures such as bone/cartilage/muscle/ vessels/nerves, allergic reactions which can be life threatening if untreated, heart irregularities, dizziness or lightheadedness, lung puncture, pneumothorax which can be life threatening, death
Procedure Risks

• There also may be other side effects that we cannot predict.
• The subject will be instructed to tell the research staff about all the medications, vitamins, and supplements you take, as well as any medical conditions they may have. This may help avoid side effects, interactions, and other risks.
Other Issues Addressed

• Safety Precautions
• Benefit vs Risk
• Available Alternative Treatments
• Research Materials, Records, and Privacy
• Confidentiality
• Payment- None
• Cost to Subjects: None, insurance will be billed, no copay
• Data and Safety Monitoring
• Subject Complaints
Resources


Resources


Thank You

• Any questions or suggestions