**The Natural History of Acute Cervical Radicular Pain**

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**Background**

Cervical radicular is a relatively common disorder characterized by upper limb pain and has been defined as pain resulting from stimulation cervical nerve roots that radiates into the upper limb and is shooting or electric in quality.” (Bogduk book 1999, IASP). A cervical radiculopathy is noted by objective neurological signs such as numbness, weakness or reflex changes. The most common cause of a cervical radiculopathy is spondyloarthrosis or a herniated disc. (Kuijper).

Studies using CT and MRI (Maigne, Bush, Vinas) have shown that over a period of time, ranging from one to 30 months, cervical disc herniations tend to diminish in size. Larger herniations show a greater reduction in size whereas small protrusions show only slight decreases if any. If there is bony foraminal stenosis from spondyloarthrosis, one might expect a less favorable outcome, although this has not been studied.

There have been mixed reports regarding the clinical natural history of cervical radicular pain. Two studies suggest a less favorable outcome. One study (Dillin) followed patients who at one year had failed conservative therapy but did not undergo surgery. At five years, 55% remained unsatisfactory and 25% were unable to return to work. Another study (Persson)followed 21 patients on a waiting list for surgery at least 10 months. Of these, 62% considered themselves unchanged or impaired. These paint a less favorable, but possibly reflect patients that are more severely affected.

Other studies portray a more favorable natural history. A population based retrospective review of 561 patients that were followed five years showed that a total of 26% underwent surgery. At last follow-up 90% were considered normal or mildly incapacitated. Recurrences occurred in 32%, but many described as only isolated recurrences. Other studies looking at physical therapy (PT) compared to no treatment or placebo treatment suggest that the majority of patients can get better with time no matter the treatment (British Assoc of Physical Med, Goldie). The downside of all of these studies is that they did not capture acute radicular pain, which makes it difficult to clarify the true natural history cervical radicular pain.

One study that did look at acute cervical radicular pain was a comparison study looking at various treatments: PT, cervical collar and no treatment. They captured patients within one month of symptom onset. They found that PT or cervical collar helped more than no treatment early on. With time, most patients tended to improve no matter what was done. (Kuijper)

**Purpose**

This study looks to clarify the natural history of acute cervical radicular pain. Additionally, this study looks to see what percentage of patients will have marked reduction in pain at specific time intervals. This study will look to clarify if age, bony foraminal stenosis or neurological deficits (motor, sensory, reflex changes) correlate with a worse ultimate outcome.

**Design**

**Sample, Setting, Recruitment, Procedure**

We will ask general practitioners and spine care physicians at a university health care center to refer patients to two investigators (Physiatrists WB and DS). Inclusion criteria for the study are patients ages 18-75, radicular pain for less than one month, pain that gets past the elbow, upper limb pain greater than neck pain, 40mm or more on the visual analog scale (VAS). Additionally, there has to be at least one positive finding on exam: provocation of upper limb pain by neural tension signs or neck movements (Spurling’s maneuver), motor, sensory or reflex changes. Motor, sensory and reflex grading will be according to the American Spinal Injury Association (ASIA) grading scales. Plain x-rays including AP, lateral oblique views will be obtained on initial evaluation. The oblique views will help characterize if there is bony foraminal stenosis. MRIs will be obtained within 4-6 weeks from onset of pain to correlate imaging findings with clinical picture.

Exclusion criteria include clinical signs of spinal cord compression, myelopathy or progressive neurological changes. Patients with psychosocial issues that might prevent participation in the study will also be excluded.

Sixty consecutive patients that meet inclusion criteria and consent will be included in the study and will be followed for one year. There will be follow-up at one, three, six and twelve months. They will be asked if their symptoms are worse, same, mildly better or markedly better compared to baseline. Patients will give their VAS (average and worse) for neck and upper limb pain. They will also fill out neck disability index. Medication use will also be documented.

Patients will have a standardized treatment that is typical for cervical radicular pain: soft cervical collar, NSAID (diclofenac) and pain medications if needed. None of these treatments have ever been shown to change the long term natural history of radicular pain (Kuijpr from above BMJ 2009, Weber Vroomen). These are palliative measures and the hope is with time symptoms will improve on their own. If symptoms are recalcitrant to conservative measures, they will have the option to talk with a spine surgeon.

**Risks to participation**

There should be no risk to patients. They will be treated with standard treatments that are currently accepted as standard of care for cervical radicular pain.

**Benefits to subject or future benefits**

A better understanding on the natural history of acute cervical radicular pain.

**Data Analysis**

A statistician will oversee data analysis. Simple analysis will be made as to what percentage of patients report marked improvement at specific intervals. Repeated-measures analyses of VAS pain scores (or neck disability index scores) using a means model with SAS Proc Mixed (version 9, mixed linear models) will be used to determine changes between baseline and follow-up visits. The independent variable in the repeated measures analyses is time on study (0, 1, 3, 6, 12 months).   The statistical model will provide separate estimates of the VAS mean pain scores by time on study.  An unstructured variance-covariance form among the repeated measurements will be assumed for the VAS pain score outcome and estimates of the standard errors of parameters will be used to perform statistical tests and construct 95% confidence intervals.

We will analyze if there is differences in outcomes based on age (older or less than 50), bony foraminal narrowing and neurological deficits (motor, sensory, reflexes changes).

**Plans for data management and monitoring. Confidentiality**

Strictest confidentiality will be kept regarding personal information (name, date of birth and results). Name and date of birth will be the linked with results. This information will be in a secure location within the office of the primary investigator. This office is kept locked during off hours.

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