Quantitative Sensory Testing (QST) in The Diagnostic & Therapeutic Process of patients with Painful Cervical Facet Arthropathy

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34812

Source
ToetsingOnline

Brief title
QST in Chronic Neck Pain

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Chronic Neck Pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cervical Facet Joint Pain, Chronic Neck Pain, Quantitative Sensory Testing

Outcome measures

Primary outcome

Our primary endpoint is to detect generalized hyperalgesia, defined as a decrease in pressure-pain thresholds (PPT) of more than 30% in a distal site (the rectus femoris muscle) outside their reported areas of pain, vs. healthy, pain-free controls. A further objective is to subsequently track the these PPT changes in this group of patients through their diagnostic and therapeutic process, to ascertain if this hyperalgesia predisposes them to poor treatment response or if this hyperalgesia in fact, abates with the ablation of the peripheral painful input. Important secondary endpoints include electrical wind-up testing and DNIC testing which provide further information regarding vulnerability to central sensitisation or it progression, and may also help predict response to therapeutic intervention. Thermal detection testing helps identify patients with nerve damage which could also predispose to central sensitization.

Secondary outcome

Secondary study parameters, in particular the rest of the QST battery, further reinforces the primary objective. Windup ratio will serve to confirm the presence of spinal central sensitisation, while measurement of the DNIC

response will allow insight into vulnerability for (further) progression of central sensitisaton. Thermal detection thresholds and electrical pain detection thresholds will help detect nerve damage which again can predispose a patient to supra-spinal central sensitization.

Because chronic neck pain, like many other chronic pain conditions, is fraught with numerous psychosocial complications, the quality of life and degree of perceived disability will also be evaluated using the following questionnaires:

1. Quality of life (1 questionnaire): SF-36 (Medical Outcomes Study Short-Form General Health Survey (Ware, Jr. and Sherbourne 1992;Aaronson et al. 1998))

2. Sleep disturbance (1 questionnaire): MOS Sleep Scale (Hays and Stewart, 1992 R.D. Hays and A.L. Stewart, Sleep measures)

3. Disability: Neck Disability Index (NDI) (H Vernon and S Mior, 1991)

Study description

Background summary

Neck pain is one of the most common chronic pain conditions encountered in modern society. In the Netherlands, neck pain complaints (in combination with back pain) are amongst the top 3 reasons that patients call on their general practitioner. The point prevalence of chronic neck pain is 110 per 1000 in men and almost 180 per 1000 in women (25 years and older, by gender, standardized to the population of Netherlands in 2000). In 2005, neck and back pain complaints accounted for 867.2 million Euros or 1.3% of total healthcare costs in Netherlands.

Koelbaek Johansen et al (1999) and Chien et al (2009) both found generalized hyperalgeisa in whiplash patients with chronic neck pain, a result compatible with generalized central sensitisation or disordered central pain processing. Such central hypersensitivity can, e.g., result in an amplification of nociceptive input arising from a peripheral focus in the neck. Cervical facetal arthropathy is considered a leading cause of both traumatic and idiopathic chronic neck pain. Hence, we have chosen to study normal clinical practice in patients with cervical facet arthropathy, with the aim of detecting supraspinal central sensitisation via generalized hyperalgesia as defined by a clinically relevant decrease in pressure-pain thresholds of more than 30% (compared to a healthy population) in a site distant from their reported areas of neck pain.

Study objective

The primary objective in this study is to detect the presence of supra-spinal central sensitization in patients with chronic neck pain secondary to cervical facetal arthropathy. We aim to show this by comparing the pressure-pain thresholds (PPT; the primary parameter) in a distal site (the rectus femoris muscle) of 69 patients which chronic neck pain secondary to cervical facetal arthropathy versus 23 age and sex-matched healthy controls. This finding is important as we have reasons to believe that central sensitization will negatively impact the outcome of therapeutic intervention in this group of patients. We aim to demonstrate this via serial QST measurements accompanying the patients* diagnostic and therapeutic process.

The measurement of the secondary study parameters, in particular the rest of the QST battery, further reinforces this primary objective. Thus determination of the windup ratio will serve to confirm the presence of spinal central sensitisation, while measurement of the DNIC response will allow insight into vulnerability for (further) progression of central sensitisaton. Thermal detection thresholds and electrical pain detection thresholds will help detect nerve damage which again can predispose a patient to supra-spinal central sensitization. Because chronic neck pain, like many other chronic pain conditions, is fraught with numerous psychosocial complications, the quality of life and degree of perceived disability will also be evaluated using the SF-36, Neck Disability Index (NDI) and MOS Sleep scale questionnaires.

Study design

The study has a cross-sectional design, and compares patients with painful cervical facet arthropathy to healthy-matched controls using a QST measurement battery. After written informed consent, the patients will be given a set of study questionnaires that require a maximum of 15 min to complete. The questionnaires include the SF-36, Neck Disability Index (NDI) and the MOS Sleep Scale. The patient will then undergo their first QST measurement. This is then followed by diagnostic block testing with both lignocaine 1% and bupivacaine

0.5%. A second QST measurement is done 1 week after the diagnostic blocks. If either of the diagnostic blocks is positive the patient will then receive a therapeutic medial branch radiofrequency denervation, otherwise, the patient will be treated conservatively. Each QST session is entirely identical to the previous, allowing serial comparisons to be made. The patients will undergo a total of 3 QST measurements: one prior to diagnostic blocks, one after diagnostic blocks and one three months after treatment. The diagnostic and therapeutic process depicted in this protocol is entirely identical to routine clinical practice.

Study burden and risks

It is estimated that the 3 specified questionnaires will take a maximum of 15 minutes to complete. Each QST session requires up to 60 min to complete. All patients presenting with chronic neck pain complaints will undergo at least QST 1. Those who are clinically diagnosed with painful cervical arthropathy will undergo another 2 QST sessions, conducted over 3 months. As the QST sessions has been integrated into our work process, the patient will only need to make an extra 2 trips compared with routine clinical practice.

Expected findings:
We anticipate that we will demonstrate generalized hyperalgesia as a sign of supra-spinal central sensitization in significant proportion patients with chronic neck pain as a result of painful cervical facet arthropathy. Accompanying this finding will be another subgroup of patients with a significant degree of windup and poor DNIC response. Our postulation is that these patients will respond more poorly to both diagnostic and therapeutic blocks.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male and female patients who are 18 years or more of age.
2. Patients with a history of chronic, function-limiting neck pain of at least 3 months duration.
3. Patients who are able to provide voluntary, written informed consent to participate in this evaluation.
4. Patients willing to return for follow-ups.
5. Patients without a history of recent surgical procedures (i.e. within the last 6 months)

Exclusion criteria

1. Patients with uncontrolled major depression or psychiatric disorders.
2. Patients with recent history of heavy opioid usage, chronic alcoholism or substance abuse.
3. Patients with acute or uncontrolled medical illness, malignancy or poorly controlled epilepsy.
4. Patients with chronic severe conditions that could interfere with the interpretations of the outcome assessments.
5. Patients with fibromylagia or painful syndromes of unknown origin or associated with diffuse pains.
6. Female patients who are pregnant or lactating,
7. Patients unable to tolerate prone or lateral position.
8. Patients with histories of adverse reactions to local anesthetic or steroids
9. Patients with anatomical abnormalities on cervical spine X-ray that may result in technical difficulties for blocks

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-12-2010
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO

Date:	19-05-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30653.091.09