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Associations between pain intensity, functional status, and beliefs and attitudes towards pain in people with chronic pain, after a lidocaine infusion.

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January, 2009

A thesis submitted to McGill University
In partial fulfilment of the requirements of the degree of Master of Science.

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Your file Votre référence
ISBN: 978-0-494-67039-2
Our file Notre référence
ISBN: 978-0-494-67039-2

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ABSTRACT

BACKGROUND: Pain intensity, functional status and beliefs and attitudes towards pain are dynamic elements involved in the experience of chronic pain. Lidocaine infusion (LI) is a therapeutic intervention used to relieve pain. **OBJECTIVES:** The primary objective of this study was to determine if people with chronic pain who received LI and reported a decrease in pain intensity at 4 days post-infusion differed from those who did not report a decrease in pain intensity with respect to the following: a) baseline beliefs and attitudes towards pain; b) changes in belief and attitudes towards pain; c) and changes in functional status. This study also investigated if these differences were associated with being a novel or repeat LI user. A secondary objective was to estimate the sample size required for a larger study. **METHODS:** This project was an exploratory study. Thirty-three subjects were monitored for pain intensity using the Visual Analogue Scale (VAS) just before the infusion, and then at four days, two weeks, and three weeks after the infusion. The subjects were separated into groups depending on the criteria of whether or not they had: a) criterion-based pain intensity decrease or not on the fourth day post infusion, and b) received a previous LI or not. Since no subjects who received their first LI reported pain intensity decrease four days later, three groups emerged from this classification: first time LI users with no pain decrease, repeat LI users with no pain decrease, and repeat LI users with pain decrease. The subjects completed two self-administered questionnaires - the Survey of Pain Attitudes (SOPA-32) and the Short Musculoskeletal Function Assessment (SMFA) - before the infusion, and at two and three weeks post-infusion. The most important change at two or three weeks post-infusion was used for comparison purposes. **RESULTS:** No significant changes in function (SMFA) were found. However, changes in specific beliefs and attitudes towards pain (SOPA-32) were associated with the group variable as follows: 1) All three groups showed a significantly stronger belief that 'others, especially family members, should be solicitous in response to their experience of pain' after the infusion. 2) Those who received their first LI and did not report pain intensity decrease also showed a significantly stronger belief that 'medications are an appropriate treatment for chronic pain' after the infusion. 3) Subjects who had previous LI and did not report pain intensity decrease were the only ones to believe significantly less that 'medications are an appropriate treatment for chronic pain'

and more 'in a medical cure for their pain problem' after the infusion. 4) Subjects who had previous LI and did report pain intensity decrease had a significantly stronger belief in the appropriateness of medications and that 'that they should avoid exercise' after the infusion. 5) Finally, subjects who believed more that 'medications are an appropriate treatment for chronic pain' and less 'that they should avoid exercise' at baseline, had significantly higher chances of experiencing decrease in pain intensity 4 days after a LI. **CONCLUSION:** The impact of a LI on the individuals' beliefs and attitudes towards pain differs depending if their pain intensity decreased or not four days after the infusion, and if they had previous LI or not. By contrast, their pre-infusion beliefs and attitudes profile impacts on the efficacy of this intervention. Because of the small sample size, the heterogeneity of the subjects in terms of the localization of their pain, and our choice of measurement tool, it is not possible to determine if LI impacts on function. Nevertheless, this exploratory study generated some novel observations and questions that are of great interest for future research. A particular question of interest would be to determine if repeated LI fosters a more passive attitude towards pain management. It was also determined that a sample size of 70 subjects per group would be necessary for future research on this question.

Keywords: Chronic pain, lidocaine, beliefs and attitudes towards pain, function, pain intensity.

RÉSUMÉ

MISE EN SITUATION: L'intensité de la douleur, le niveau fonctionnel ainsi que les croyances et attitudes envers la douleur sont des éléments en interaction dans l'expérience de la douleur chronique. L'infusion de lidocaïne (IL) est une intervention thérapeutique utilisée pour soulager la douleur. **OBJECTIFS:** L'objectif principal de cette recherche était de déterminer si parmi les personnes présentant un problème de douleur chronique qui reçoivent une IL, celles qui ont rapporté une diminution de l'intensité de la douleur quatre jours après l'infusion différaient de celles qui n'ont pas rapporté de diminution de douleur, en ce qui concerne: a) leurs croyances et attitudes initiales envers la douleur; b) les changements au sein de leurs croyances et attitudes envers la douleur; c) et les changements de leur niveau fonctionnel. Il s'agissait également de déterminer si ces différences étaient dues au fait de recevoir une première ou une nouvelle infusion. Le second objectif était d'estimer la taille d'échantillon requise pour une étude plus vaste. **MÉTHODOLOGIE:** Ce projet consistait en une étude exploratoire. Trente-trois sujets ont rapporté l'intensité de leur douleur sur une échelle visuelle analogue avant l'infusion, ainsi qu'à quatre jours, deux semaines et trois semaines après l'infusion. Chaque sujet a été assigné à un groupe selon qu'il avait ou non: a) rapporté une diminution de l'intensité de la douleur quatre jours après l'infusion, et b) déjà reçu une IL. Trois groupes ont émergé de cette classification puisque aucun sujet ayant déjà reçu une IL n'a rapporté une diminution de douleur: première IL sans diminution de douleur, nouvelle IL sans diminution de douleur, et nouvelle IL avec diminution de douleur. Les sujets ont complété deux questionnaires auto-administrés - le Questionnaire sur les attitudes envers la douleur (QAD/F-SOPA-32) et le Questionnaire d'Évaluation de la Fonction Musculo-Squelettique (version courte) - avant l'infusion, ainsi qu'à deux et trois semaines après l'infusion. Le plus grand changement, à deux ou trois semaines après l'infusion, a été retenu à des fins d'analyse. **RÉSULTATS:** Aucun changement significatif du niveau fonctionnel n'a été décelé. Cependant, des changements de croyances et attitudes envers la douleur ont été décelés chez certains groupes: 1) les trois groupes ont démontré une croyance significativement plus forte que «les autres, particulièrement la famille, devraient montrer de la sollicitude en réponse à leur expérience de la douleur» suite à l'infusion. 2) Les sujets ayant reçu une première infusion de lidocaïne et n'ayant pas

rapporté une diminution de l'intensité de la douleur ont démontré une croyance significativement plus forte que «les médicaments constituent un traitement approprié pour la douleur chronique» suite à l'infusion. 3) Les sujets ayant déjà reçu une infusion de lidocaïne et n'ayant pas rapporté une diminution de l'intensité de la douleur étaient les seuls à croire significativement moins que «les médicaments constituent un traitement approprié pour la douleur chronique» ainsi qu'à croire significativement davantage «en une guérison médicale de leur douleur» suite à l'infusion. 4) Les sujets ayant déjà reçu une infusion de lidocaïne et ayant rapporté une diminution de l'intensité de la douleur ont démontré une croyance significativement plus forte que «les médicaments constituent un traitement approprié pour la douleur chronique» et «qu'ils devraient éviter de faire de l'exercice» suite à l'infusion. 5) Enfin, les sujets qui croyaient davantage que «les médicaments constituent un traitement approprié pour la douleur chronique» et qui croyaient moins «qu'ils devraient éviter de faire de l'exercice» avant l'infusion, ont eu des chances significativement meilleures de rapporter une diminution de l'intensité de la douleur quatre jours après l'IL. **CONCLUSION:** L'effet d'une IL sur les croyances et attitudes envers la douleur diffère chez les individus selon qu'ils rapporté une diminution de l'intensité de la douleur ou pas après l'infusion, et qu'ils aient déjà reçu une IL ou non. Inversement, leurs croyances et attitudes initiales envers la douleur influencent l'efficacité de cette intervention. Étant donné la petite taille de l'échantillon, son hétérogénéité en terme de localisation de la douleur ainsi que l'instrument de mesure utilisé, il n'est pas possible de déterminer si l'IL a un effet sur le niveau fonctionnel. Cependant, cette étude exploratoire a soulevé de nouvelles interrogations qui sont d'un grand intérêt pour d'éventuelles recherches auprès de cette population. Une question particulièrement importante serait de déterminer si des IL répétées favorisent une attitude plutôt passive du patient en ce qui a trait à la gestion de sa douleur. Cette étude a également permis de déterminer qu'un échantillon comprenant soixante-dix sujets par groupe serait requis dans le cadre d'une étude plus vaste.

Mots-clés: Douleur chronique, lidocaïne, croyances et attitudes envers la douleur, fonction, intensité de la douleur.

ACKNOWLEDGEMENTS

I am particularly grateful for the constant and relevant support I received from my supervisor, Patricia McKinley, Ph.D. She became an inspiring model of rigor and professionalism to me.

Josée Duquette, M.Sc., O.T., also played an essential role in the achievement of this project. Her expertise certainly improved the clinical relevance of this research.

Ann Gamsa, Ph.D., and Yoram Shir, M.D., had a notable influence on the set up and progression of this research. I also sincerely acknowledge their consent for the introduction of occupational therapy in this specialized clinical setting.

Bobby Popovec, M.D., Louise Lamb, R.N. inf., Mary Griffin BscN., N inf., and France Ellyson, R.N. inf., precious collaboration made a considerable difference when it came to data collection.

Very special thanks to Julie Lamoureux, DMD, M.Sc. who has kindly and efficiently helped me with the statistics and to Michèle Modjo for her involvement in the data compilation.

As well, le Centre Professional d'Ergothérapie facilitated my commencement of this degree and helped me acquire a solid clinical experience which certainly triggered my motivation to do research in the field of chronic pain.

I am also very grateful to each patient who agreed to take part of this research.

To my dear parents, wonderful husband, and lovely son, I am filled with gratitude for your steady encouragement.

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1. INTRODUCTION

Pain is a sensory and emotional experience (Merskey, Lindblom, Mumford, Nathan, & Sunderland, 1994). When pain persists, this distressing experience can be associated with alterations in the person's functional status and changes in her attitudes. In turn, attitudes influence pain and its impact on function. Pain intensity, functional status, and beliefs and attitudes towards pain are dynamic elements involved in people living with chronic pain. Multidisciplinary pain clinic programs aim to reduce pain and enhance function by considering the multidimensional components of chronic pain. Lidocaine infusion (LI) is one of the therapeutic interventions used to relieve pain. However, little has been done to identify the patients most likely to benefit from LI (Carroll, Gaeta, & Mackey, 2007). As well, its impact on function has never been explored. Furthermore, it is unknown if interactions exist between beliefs and attitudes towards pain and changes in pain intensity following a LI. In the original plan, based on reports from the MUHC Pain Centre, it was determined that we could recruit approximately 60 first time LI users within a three month period. However, monitoring of the intake at the Pain Centre prior to proposal presentation indicated that this was not the case, and that most of the patients were repeat LI users. The committee decided to enlarge the research question to include both novel and repeat LI users, and this amendment was approved by the GEN-Research Ethics Board prior to starting data collection. As well, it was thought prudent to extend the recruitment period to seven months. This change is reflected in the research questions and hypothesis presented in the thesis.

This exploratory study aims to explore the associations between changes in pain intensity, in function and in beliefs and attitudes towards pain in patients receiving a LI. A second objective is to estimate the sample size required for a larger study. It is important to note that neither the efficacy nor the effectiveness of the treatment is assessed here.

2. LITERATURE REVIEW

Chronic non-cancer pain is common in adults. A recent Canadian survey (Boulanger, Clark, Squire, Cui, & Horbay, 2007) estimated its prevalence at 22% for men and 27% for women in Canada. Pain is considered as chronic when it lasts for more than three consecutive months (Moulin, Clark, Speechley, & Morley-Forster, 2002). The World Health Organization's *International Classification of Functioning, Disability and Health* (http://www3.who.int/icf/) is a conceptual framework used to classify the consequences of disease components of health. Using this terminology, an altered *body structure* (e.g. joint) *and function* (e.g. mobility) refers to impairment (e.g. stiffness), *activity limitation* applies to an altered performance of a task or action (e.g. self-care) and *participation restriction* signifies altered involvement in life situations (e.g. work). "Functioning" is an umbrella term referring to the positive aspects of these three dimensions whereas "disability" is the antonym. In this study, we will adopt "functional status", "function" and "disability" as umbrella terms when referring to the person's ability or difficulties to perform activities.

The *International Classification of Functioning, Disability and Health* allows us to conceptualize chronic pain as an impairment that is often associated with loss of strength, diminished range of motion and sensory deficits of the involved body part(s). People living with chronic pain problems can be limited regarding their movements, their mobility and/or their ability to perform certain activities of daily living. A major Canadian survey of persons with disabilities has been conducted in 2001 (http://dsp-psd.pwgsc.gc.ca/Collection/RH37-4-4-2001F.pdf): the Participation and Activity Limitation Survey. Based on the World Health Organization's definition, people included in this survey were considered as having a disability if they had a "physical or mental condition or a health problem that restricts their ability to perform activities that are normal for their age in Canadian society" (section 2). They found that 10% of adults (15 years old and over) had disabilities due to chronic pain. Moreover, the survey made by Boulanger et al. (2007) revealed that chronic pain interfered with day-to-day life to some extent in 40% of respondents and to a large extend in 28% of them.

2.1 Pain definition and conditions

Pain is first and foremost an adaptive sensation, a warning to protect the body from tissue injury (Scholz and Woolf, 2002). Acute pain occurs when a harmful stimulus affects body tissues and gradually subsides during the healing process. Chronic pain is pain that extends beyond the expected period of healing. A duration of three months is typically used to distinguish chronic from acute pain (Moulin, Clark, Speechley, & Morley-Forster, 2002).

2.1.1 Nociceptive pain (somatic and visceral)

Somatic pain is due to muscle, bone, joint, skin and/or ligament damage. The Canadian Pain Society (Moulin et al., 2002) describes musculoskeletal pain as "a dull annoying ache, and occasionally as sharp, like a knife stab. It varies predictably with use of the affected area. It commonly interferes with sleep and the pursuit of leisure, social and employment activities." (p. 145). It includes arthritic conditions, fibromyalgia, bursitis, tendonitis, osteoarthritis and acute trauma (wrist, rib, spine or hip fractures). Chronic low back pain, chronic neck pain due to whiplash injury, chronic shoulder-arm pain, and the myofascial pain syndrome may also be included, if a musculoskeletal structure was originally injured. Regarding visceral pain, it comes from injuries to the gastro-intestinal tract, pancreas or other internal organs. Visceral pain can be sharp or aching, is diffuse and often poorly localized. This category includes abdominal pain, pancreatic pain and menstrual cramps, for example.

2.1.2 Neuropathic pain (peripheral and central)

Pain that is initiated or caused by a primary lesion or dysfunction in the nervous system is called neuropathic pain (Merskey et al., 1994). The symptomatology of neuropathic pain includes spontaneous pain, allodynia, dysesthesia and hyperalgesia (Backonja & Galer, 1998). Pain can be perceived in the absence of noxious stimuli, and occasionally in the absence of any stimuli (Markman & Oaklander, 2002). It is often described as a burning, shooting, electrical or tingling pain. Neuropathic pain conditions are classified as being peripheral or central depending on the localisation of the damage.

Peripheral neuropathic pain occurs when the peripheral nervous system is initially damaged. It can be caused by trauma, diseases or poisons. On the other hand, central neuropathic pain occurs when the primary insult affects the central nervous system. It can be due to stroke, spinal cord injury and may occur during the course of multiple sclerosis, brain injury or any trauma to the central nervous system.

When pain becomes chronic, neuropathic pain conditions usually involve both central and peripheral mechanisms. The seven most common neuropathic pain conditions from the most to the least prevalent are as follows: low back pain, diabetic neuropathy, post-herpetic neuralgia, complex regional pain syndrome, multiple sclerosis, phantom pain and trigeminal neuralgia (Markman & Oaklander, 2002). These pain conditions are often differentiated from one another using the following descriptors: 1) Low back pain has different aetiologies (muscle strain, spinal degenerative diseases such as disc herniation, spinal deformities, trauma, or systemic problems) and can be maintained over time because of neuropathic pain mechanisms. 2) Diabetic neuropathy involves one or many nerves. Pain onset follows sensory deficits and often involves the feet first. 3) Post-herpetic neuralgia occurs when pain does not resolve after a herpes zoster or shingles infection. Most cases involve the thoracic dermatomes. It is can also affect the face, neck and arms. 4) The complex regional pain syndrome (CRPS) mostly affects the limbs. There is no identifiable initial nerve injury in CRSP type I (reflex sympathetic dystrophy) while CRPS type II (causalgia) is triggered by a nerve injury. This pain syndrome is characterized by spontaneous and stimulus-evoked pain, oedema, vasomotor and sudomotor abnormalities, motor dysfunction, and trophic changes. 5) Multiple sclerosis can lead to diffuse body pain due to central neuropathic pain. Recurrent headaches are common with these patients. 6) Phantom pain which is the illusive sensation of a limb that occurs when the sensory roots have been destroyed and occurs in up to 50% of all amputees (Markman & Oaklander, 2002). 7) Trigeminal neuralgia often involves compression of the trigeminal nerve that leads to electric shock or stabbing pain in an area of the face. Baron and Tolle (2008) recently propose a classification of neuropathic pain based on pain and sensory symptoms that could supplement the traditional classification that was based on disease entities, anatomical localization or histological observations.

2.1.3 Idiopathic pain

Idiopathic pain refers to chronic pain conditions from unknown origins. Previously mentioned diagnoses were included in this category when their aetiology was unknown.

2.2 Pain mechanisms

Pain pathways include nociceptive peripheral nerve fibres, specific regions of the spinal cord and different areas of the brain. Damaged tissues release neurotransmitters and inflammatory mediators that activate surrounding nociceptors. Then, these nociceptors (C-fibres and A-& fibres) transmit painful information to the dorsal horn of the spinal cord where mechanisms involving sodium ion gate channels allow interneuron modulation of the pain signal (Warfield & Fausett, 2002). According to the gate control theory of pain published in 1965 by Melzack and Wall (1965), non painful information conducted by larger fibres, such as mechanical and thermal stimulation, can decrease the pain signal at the spinal level. In turn, second-order neurons pass to the anterior region of the contralateral side of the spinal cord and send the pain signal to the brain through spinal-pain tracts. At this level, pain modulation occurs under the positive and negative influences of the reticular formation, the hypothalamus, the thalamus and the limbic forebrain structure. According to this theory, descending influences from the brain also play an important role in pain signal modulation at the level of the spinal cord. In 1978, Melzack and Loeser (1978; Melzack, 1999) published a newer model, consistent with the gate control theory, which highlights the brain processes involved in pain modulation. The 'neuromatrix' consists of a widely distributed neural network in the brain. It is initially determined genetically and later modified by sensory, cognitive, emotional and hormonal inputs. The output of this matrix of neurons, the "neurosignature", determines different qualities and properties of the pain experience (Melzack, 2004; Nielson, 2001; Sullivan, 2008).

Pain becomes maladaptive when neurophysiologic mechanisms generate spontaneous and exaggerated pain that has no protective role. Chemical and physical "rewiring" of the nervous system, or neuroplasticity, occurs following injury and/or

inflammation because of continued stimulation of receptors in the periphery, the spinal cord and also in brain centres. These repeated painful stimulations induce changes in balance of neurotransmitters and depolarisation of specific peripheral nociceptors' receptors that become more easily excitable. The increased pain signals are transmitted to the dorsal horn of the spinal cord and result in hyperexcitability of spinal interneurons and increased pain signals to the brain. Changes in balance of neurotransmitters in specific areas of the brain result in increased pain perception (Moulin et al., 2002). This hyperexcitability state may also impact on genetic expression, which can influence the long-term changes in cellular function, e.g. development of "pain memory" (Melzack, 1999). These mechanisms lead to lowered pain threshold, higher pain signal and wider localisation of pain and contribute to the development of chronic pain syndromes. The neuromatrix theory helps explain chronic pain syndromes, which are often characterized by severe pain associated with little or no discernible injury or pathology (i.e. phantom limb pain). This theory supports the importance of brain processes that may be generated in the absence of sensory input and trigger neurosignature patterns that maintain pain mechanisms (Coderre, Katz, Vaccarino, & Melzack, 1993). Indeed, in a recent review, Apkarian, Bushnell, Treede, and Zubieta (2005) determined that the pain perception in normal vs. chronic pain patients is at least in part distinct, and that chronic pain may engage areas of the brain that are active in cognitive-emotional assessments. As well, with the onset of fMRI studies, researchers are beginning to get a better idea of the way in which brain activity and neurochemistry may be altered. In a very recent review (Seifer, & Maihöfner, 2008), Baliki, Geha, Apkarian, and Chialvo (2008) were cited as proposing that chronic pain affects functional connectivity of cortical regions known to be active at rest. They noted that despite being able to perform a visual attention task equally as well as control subject, persons with chronic back pain demonstrated a reduced deactivation in some of those brain regions. It was suggested that these disruptions may underlie impairments in cognitive and behavioural features of the individual who experiences chronic pain.

Chronic pain symptomatology includes a variety of signs and symptoms. Merskey et al. (1994) have published a list which includes the following definitions. Allodynia is "pain due to a stimulus which does not normally provoke pain" (p. 210). Hyperalgesia is

"an increased response to a stimulus which is normally painful" (p. 211), whereas hypoalgesia is the opposite. Dyesthesia refers to "an unpleasant abnormal sensation, whether spontaneous or evoked" (p. 211); allodynia and hyperalgesia are special cases of dysesthesia. Pain is spontaneous or evoked and can spread on a wider area than the localization of the initial damage (i.e. referred pain).

2.3 Pain and Function

Physical and psychosocial factors are constantly interacting with pain perception. Beliefs and attitudes towards pain, motivation, emotions, past experiences, cultural background, physical and social environment are important factors affected by and involved in pain processing at the brain level.

2.3.1 Physical function

Persons living with chronic pain problems often face difficulties performing activities such as self-care, dressing, household tasks, writing, driving and working, for example. Studies have been conducted to see if pain was an important determinant of function. Vlaeyen, Kole-Snijders, Boeren, and van Eek (1995), report that many studies have shown little direct relationship between pain and disability. Rainville, Ahern, Phalen, Childs, and Sutherland (1992) did a longitudinal study with patients with disabling chronic low back pain receiving a functional restoration rehabilitation program that consisted in daily exercises that were gradually increased regardless of subjective pain. They measured pain and physical performance (flexibility, lifting capacity and endurance) before and after the program and found significant improvement in physical performance with no significant pain decrease. Another study by Moran and Strong (1995) revealed that patients with chronic back pain showed a significant reduction in the perceived level of disability and a significant increase in functional capacity after discharge from a rehabilitation program without significant change in perceived pain intensity. Recently, Alschuler, Theisen-Goodvich, Haig, and Geisser (2007) also noted an absence of a significant relationship between pain intensity and physical performance in a group of 267 patients with chronic disabling pain.

Because it seems that level of function is not directly linked to pain intensity, it becomes necessary to investigate other factors that may be associated with changes in a person's functional status. In this study, we are interested in beliefs and attitudes towards pain.

2.3.2 Pain Beliefs and Attitudes

The Gate-Control Theory recognizes the interaction between sensory, affective and cognitive dimensions of pain (Melzack & Wall, 1965). Villemure & Bushnell, 2002 stated that "attentional state, emotional context, hypnotic suggestions, attitudes, expectations or anesthesia-induced changes in consciousness now have been shown to alter both pain perception and forebrain pain transmission in humans" (p. 195). These authors suggest that pain sensation and pain unpleasantness are modulated through multiple and not fully known neural mechanisms that occur in the limbic and/or sensory brain regions; they point out that pain can be perceived as less intense when an individual's attention is distracted to another sensory modality than pain, such as a visual, auditory or tactile stimulus. By contrast, pain itself modifies the ability to focus attention (Miron, Duncan, & Bushnell, 1989). As well, emotional states and attitudes of patients have been shown to have an effect on pain associated with chronic diseases (Haythornthwaite & Benrud-Larson, 2000; Schanberg et al., 2000). Results from a study with people with HIV (Evans, Weinberg, Spielman, and Fishman, 2003) revealed significant associations between negative cognitions and pain intensity and showed that negative cognitions predicted interference in daily functional activities, overall distress and affective symptoms. A recent study by Alschuler et al. (2007) examined the relationships between self-report measures of depressive symptoms, perceived disability, and physical performance among persons with chronic pain. The authors found that depression significantly contributed to self-report disability and physical performance even when controlling for age, gender, site of pain, and pain intensity.

As well, functional magnetic resonance imaging (fMRI) studies demonstrate this interaction and lend support to the neuromatrix theory of pain (Brooks & Tracey, 2005; Apkarian et al., 2005). One study showed that activation of specific regions of the central nervous system are directly proportional to pain intensity and can be modified with

cognitive therapeutic interventions (Rainville, Duncan, and Bushnell, 2002). Another study focussed on how attention modulates pain and showed that many areas of the neuromatrix displayed reduced activation, and pain intensity was reduced when subjects were distracted during painful stimulation (Bantick et al., 2002). A third study that investigated how anxiety impacts on pain perception (Ploghaus, Narain, and Beckmann, 2001) identified a region of the brain that is responsible for producing anxiety-induced increased pain perception.

According to Jensen, Romano, Turner, Good, and Wall (1999), a growing body of empirical research yielded significant associations between measures of pain beliefs and measures of functioning among patients with chronic pain. Catastrophizing thoughts have been shown to be associated with heightened pain intensity and disability and to predict disability better than pain (Sullivan et al. 2001). In more recent studies, (Sullivan, Lynch, & Clark, 2005) it was found that "catastrophizing predicted pain-related disability over and above the variance accounted for by pain severity" (p. 310) and that higher levels of pain-related empathic accuracy by the spouse were associated with negative adaptational outcomes for chronic pain patients (Gauthier, Thibault, & Sullivan, 2008).

Waddell, Newton, Henderson, Somerville, and Main (1993) found that subjects with chronic low back pain show little direct relationship between pain (intensity, total duration and anatomical pattern) and disability. However, they found a strong relationship between fear-avoidance beliefs and limitation in activities of daily living, suggesting that "fear of pain and what we do about pain may be more disabling than pain itself" (p. 164). Kinesiophobia, or fear of movement/ (re)injury, is also known to be significantly associated with disability across various types of pain (Pells et al., 2007; Burwinkle, Robinson, & Turk, 2005), especially with respect to baseline fear of movement/ (re)injury which is predictive of future perceived disability in a prospective cohort (Swinkels-Meewisse et al., 2006). By contrast, early kinesiophobia does not seem to be predictive of the duration of neck symptoms after motor vehicle collision (Buitenhuis, Jaspers, & Fidler, 2006). One important aspect impacting on kinesiophobia are self-efficacy beliefs concerning the ability to engage in a number of basic activities. It has been shown that self-efficacy beliefs can partly mediate the relationship between pain intensity and

disability (Arnstein, Caudill, Mandle, Norris, & Beasley, 1999; Arnstein, 2000) for performance of ADLs, and can mediate the relation between pain-related fear (fear of movement and catastrophizing) and pain intensity and between pain-related fear and disability (Woby, Urmston, & Watson, 2007) in a group of chronic low back pain patients. Thus it is suggested that when self-efficacy is high, elevated pain-related fear might not lead to greater pain and disability and concomitantly when self-efficacy is low, elevated pain-related fear is likely to lead to greater pain and disability. The coping strategies that the individual employs in order to manage their pain are also associated with function and specific cognitions (Nielson & Jensen, 2004; Roth & Geisser, 2002; LaChapelle, Hadjistavropoulos, & Dever, 2005; Osborne, Jensen, Ehde, Hanley, & Kraft, 2007; Jensen, Turner & Romano, 2000; Turner, Jensen, & Romano, 2000).This aspect will be expanded below and in the methodology. It also seems reasonable to (http://www.iforum.umontreal.ca/Forum/20052006/20051003/souffrir.html) that the same psychological factors related to musculoskeletal pain, such as fear, anxiety and helplessness, play a major role in neuropathic pain syndromes.

For patients with musculoskeletal pain, the Pain Brief Screening Instrument was recently developed to predict disability status during an 8 months interval (Sandborgh, Lindberg, & Denison, 2007). It includes measures of disability, self-efficacy, fear of movement and catastrophizing. Whether this tool could be useful for all types of chronic pain patients has not been well explored.

A more universal and well studied tool that has been used for the past 20 years to measure beliefs and attitudes towards pain is the Survey of Pain Attitudes (SOPA) which was developed by Jensen, Karoly, and Chant (1987). This tool and its subscales measure patients' own conceptualization of their pain experience (Williams & Thorn, 1989), which plays an important role in the development of chronic pain, disabilities, and receptivity to therapeutic interventions. It has been suggested that tools such as this can be used to better tailor the treatment approaches (Denison, Asenlöf, Sandborgh, & Lindberg 2007; Asenlöf, Denison, & Lindberg 2005). The SOPA was developed to address the need to evaluate beliefs and attitudes towards pain using a formal and empirical methodology that has measurable psychometric properties. The authors of this

self-administered questionnaire did a longitudinal study using the SOPA to assess the associations between changes in patients' specific pain-related beliefs and changes in patients functioning and behaviour after a multidisciplinary pain treatment (Jensen et al., 1999). The cognitive-behavioural model of the patient's adjustment to chronic pain suggests that a patient's functioning may be affected by certain beliefs and that changes in pain-related beliefs are associated with changes in measures of the patient's functioning. In this study, as well as in other studies (Strong, Ashton, Cramond, & Chant, 1990; Jensen & Karoly, 1992; Jensen, Turner, Romano, & Lawler, 1994; Jensen et al., 2000), significant associations were found between specific pain-related beliefs and patient-rated measures of function. However, because of the methodology used in these studies (cross-sectional designs) these findings do not imply causal relationships (Jensen et al., 1999). Therefore, it was not possible to determine if changes in pain beliefs precede, follow or occur simultaneously with changes in pain intensity and in function.

Using the SOPA, Strong et al. (1990) studied the relationships between pain intensity, functional status and beliefs and attitudes towards pain in patients with chronic low back pain. They measured these variables upon the patients' admission to hospital. No significant correlations were found between pain intensity and functional status, while significant correlations were found between functional status and specific beliefs and attitudes towards pain such as the person's beliefs if they can control their pain and if they are disabled by their pain. In this study, an increase in the belief that 'they are disabled by their pain' and a decrease in the belief that 'they can control their pain' were associated with an increase in dysfunction. They also found a significant association between an increase in the belief that 'others should be solicitous in response to their experience of pain' and an increase in pain intensity. A similar study in patients with fibromyalgia (Nielson & Jensen, 2004) found that an increased sense of control over pain, a belief that one is not necessarily disabled by fibromyalgia and that pain is not necessarily a sign of damage are important predictors of a multidisciplinary fibromyalgia treatment program outcomes (pain severity, activity level, emotional distress and life interference) up to 6 months post treatment. Another study using the SOPA (LaChapelle et al., 2005) found that "perceptions of harm, disability, appropriateness of medication, and belief in a Medical Cure were associated with higher levels of passive

coping (e.g., guarding, resting, asking for assistance, seeking social support) and with lower levels of active, problem-oriented coping (e.g., task persistence, exercise)" (p. 102) in individuals with arthritis and fibromyalgia. Also, Roth and Geisser (2002) suggest that pain-related cognitions mediate the relation between lower level of educational achievement (LOE) and more severe disability; "persons with lower LOEs possessed a greater belief that pain is a 'signal of harm'... and they also endorsed more passive and maladaptive coping strategies, including a tendency to catastrophize about their pain" (p. 286). Lastly, Jensen et al. (1994) found positive associations between the Physical Dysfunction scale of the Sickness Impact Profile (Bergner, Bobbitt, Carter, & Gilson, 1981) and two beliefs of the SOPA; a) that 'one is disabled by pain', and b) that 'pain signifies damage and that exercise should be avoided'. Similarly, they found the same pattern between the Psychosocial Dysfunction scale and three SOPA subscales; the beliefs a) that 'emotions impact the experience of pain', b) that 'others should be solicitous in response to their experience of pain', and c) that 'one is disabled by pain'.

2.3.3 Psychosocial issues

Social support is a key element for adaptation to chronic disease (Gil, Keefe, Crisson, and Van Dalfsen, 1987). In this study, although there was no difference in pain rating for subjects with high versus low satisfaction with social support, the individuals reporting high satisfaction with social support actually exhibited significantly more pain behaviours such as guarding, bracing, rubbing, grimacing and sighing. López-Martínez, Esteve-Zarazaga , and Ramírez-Maestre (2008) were also interested in the importance of psychosocial factors in adjustment to chronic pain. They found that the patient's satisfaction with social support is significantly associated with a less depressed mood and lower pain intensity, but not with functional disability. This study also revealed a modest but significant association between higher levels of perceived social support and less passive pain coping strategies. Other recent studies provide empirical support for a biopsychosocial understanding of chronic pain. Osborne, et al. (2007) studied a group of 125 persons with multiple sclerosis and pain. They found that psychosocial variables (pain-related catastrophizing, perceived social support, pain beliefs and pain coping) accounted for 25% of the variance in average pain intensity, for 22% of the variance in

pain-related interference with functioning and 43% of the variance in psychological functioning, after controlling for demographic and disease-related variables. Bolwijn, van Santen-Hoeufft, Baars, and van der Linden. (1994) revealed that social network of patients with fibromyalgia are more restricted than those of rheumatoid arthritis patients, as in contrast to rheumatoid arthritis which is a well-known disease with a well-defined aetiology, fibromyalgia is a poorly understood syndrome by both doctors and family caregivers. This lack of appreciation for the syndrome leaves fibromyalgia patients feeling isolated and misunderstood, impacting on their ability to manage pain (Bolwijn et al., 1994).

According to some authors (Giardino, Jensen, Turner, Ehde, & Cardenas, 2003; Thorn, Ward, Sullivan, & Boothby, 2003) the social context of individuals with chronic pain influences how they express catastrophizing. Giardino et al. (2003) found "a stronger positive association between catastrophizing and sensory, but not affective, pain reports among subjects who lived with a spouse or partner than those who lived with someone else. Thus, individuals may be more likely to express catastrophizing responses to sensory pain experiences in close relationships. This may be because these relationships carry a higher reinforcement value, represent a more established learning history, or are perceived as a safe context in which to express pain-related catastrophizing" (p. 23). As well, Thorn et al. (2003) emphasize the importance of understanding catastrophizing within its social context.

Chronic pain also has major socioeconomic implications; it is often responsible for work absenteeism and loss of employment. Chronic pain accounts for three quarters of the overall costs of health care and compensation (www.wcb.ns.ca/chronicpain.pdf) in Canada. According to the Canadian Pain Society, "chronic pain costs the economy approximately $14,744 per person affected per year... indirect costs, such as long-term disability payments were highest for musculoskeletal disorders, such as arthritis and chronic back pain... this would translate to an estimated $6 billion cost annually to our economy" (p. 1) (www.canadianpapinsociety.ca/PressReleaseCPSNov82005).

Chronic pain can result in a diminution in or a withdrawal from significant rewarding activities, such as work and physical and social activities. In those cases it has

a detrimental impact on quality of life. Lamé, Peters, Vlaeyen, Kleef, and Patijn (2005) found that a sample of heterogeneous pain patients reported low quality of life in each of the eight domains of health as measured by the Dutch translation of the Sf-36 (Aaronson et al., 1992). The localisations of pain of these 1208 subjects were classified in five clusters: headache, neck pain and/or brachialgia, back pain and/or sciatica, other pain, and a cluster with all possible combinations of the first four clusters (multiple pain localisations). Differences have been found within these clusters regarding the scores of almost each quality of life domain. For example, those with back pain and multiple pain localisations experienced more functional limitations. In support of Sullivan's hypothesis that catastrophizing is the best predictor of disability (Sullivan et al., 2005), they found that "pain catastrophizing showed the strongest association with quality of life, and stronger than pain intensity" (p. 15). A significant correlation has been found between pain and diminished health-related quality of life in people with slowly progressive neuromuscular disease (Abresch, Carter, Jensen, & Kilmer, 2002) and with people with knee osteoarthritis (Rucker & Metzler, 1995). Other factors, however, also come into play when considering the impact of stressors on the quality of life of adult patients with chronic pain. For example, in a pilot study, Gerstle, All, and Wallace (2001) found that "a higher quality of life was associated with subjects who were older, female, and employed, whereas a lower quality of life was associated with subjects with a low income, higher treatment costs, and a lack of workmen's compensation insurance" (p. 98). Thus the effect of chronic pain on quality of life can be related to socioeconomic factors as well as psychosocial factors. However, in Canada, the latter three may not be contributing factors due to universality of health care.

2.4 Pain Management

According to the Canadian Pain Society (Jovey, 2002), "in chronic pain problems, achieving the best outcome for the patient often involves a variable blend of pharmacological and non-pharmacological approaches that address the multidimensional components of living with chronic pain" (p. 17). Multidisciplinary pain clinic programs consider the multidimensional nature of chronic pain. According to The Massachusetts General Hospital Handbook of Pain Management (2002), these programs aim to reduce

pain and increase activity level. From the above review, a focus on promoting appropriate and sound beliefs and attitudes towards pain, such as decreasing catastrophizing, facilitating distraction, gradually increasing activity level, and establishing solid social networks would also be important adjuncts to a pain management program.

In an interdisciplinary setting, health professionals aim to achieve these common goals with the patient (Stanos & Houle, 2006). The team may include all or some of the following health professionals: physicians, dentists, nurses, psychologists, social workers, occupational therapists, physical therapists, and vocational and rehabilitation counsellors. A biopsychosocial assessment is first completed. Then, various interventions can be provided to patients (medication, anaesthetic techniques, psychological intervention, rehabilitation...). Pain programs differ in length and in content depending on the structure of the clinical settings and other factors. For example, the Royal National Hospital for Rheumatic Diseases in Bath, UK, offers three different group-based interdisciplinary treatments: 3-week residential program, 4-week residential program and 3-week hospital-based format (Koegh, McCracken, and Eccleston, 2005). "Patients are assigned to treatment groups by a clinical psychologist based on interview, observation, and psychometric assessment, of their level of psychological distress and physical disability" (p. 38).

Other programs, such as the University of Washington Pain Center's outpatient program (Jensen, Nielson, Turner, Romano, & Hill, 2004), last 3 weeks and includes "physical therapy, occupational therapy, individual cognitive-behavioral psychotherapy, vocational counselling (if indicated), group pain education and coping skills training, and the tapering of opioid and sedative-hypnotic medications (when indicated)" (p. 87).

Various interventions are offered at the MUHC Pain Centre. In addition to the initial interview with a physician, a consultation with a nurse is carried out and a psychological evaluation may be required. Then, a plan is tailored to fit each patient's therapeutic needs. It may include medication, blocks, infusions, trigger point injections, pain management group and counselling (depression management, anger management, sleep disorders management, visualisation, relaxation, meditation, coping abilities, pacing

activities strategies, etc), physiotherapy, TENS trials and education with the nurse (pain mechanisms, nutrition, medication and side effects, etc). One of the anaesthetic strategies used to decrease pain intensity is lidocaine infusions (LI). It is mostly used with patients with various pain conditions who show diffuse or localized allodynia and hyperalgesia. The SOPA is not used at the MUHC Pain Centre. Therefore, beliefs and attitudes towards pain are not systematically considered while establishing each patient therapeutic plan. Also, occupational therapy is not part of this interdisciplinary setting.

2.5 Lidocaine

Lidocaine is a local anesthetic agent of the amine type that is used for local anesthesia (Tremont-Lukats, Teixeira, & Bakonja, 2003). It has often been suggested that the analgesia occurs "by blockade of sodium ion gate channels at peripheral and central levels, specifically in the spinal dorsal horn" (p. 1). Nevertheless, "the cellular mechanisms underlying such central effects of lidocaine are largely unknown" (p. 573) (Attal et al., 2000).

Systemic lidocaine was first used in cancer pain management (Gilbert, Hanson, and Brown, 1951) and acute post-operative pain management (De Clive-Lowe, Desmond, and North, 1958; Bartlett & Hutaserani, 1961). According to Tremont-Lukats et al.' protocol for a Cochrane Review (2003), several clinical trials have found that lidocaine infusions can be an effective analgesic strategy for neuropathic pain. These studies also show that some patients with neuropathic pain respond better than others. According to Galer, Miller, and Rowbotham (1993), patients with peripheral neuropathic pain are much more likely to report pain relief with intravenous lidocaine infusion than patients with pain from central nervous system injury. Authors of this study argue that "the analgesic mechanism of systemic lidocaine in peripheral nervous system (PNS) injury is through suppression of ectopic impulse generators in damaged peripheral nerves" (p. 1234). On the other hand, Attal et al. (2000) found that "IV [intravenous] lidocaine can produce significant analgesic effects in patients with central neuropathic pain attributable to stroke or spinal cord injury" (p. 571). These authors consider that the analgesic effect of lidocaine mainly occurs at the spinal cord level. According to previous animal studies

(Woolf & Wiesenfeld-Hallin, 1985; Mao & Chen, 2000), systemic lidocaine would decrease C-fibre activity but not A-fibre-evoked activity in wide-dynamic-range neurons in the spinal cord. Another animal study (Pertovaara, Wei, & Hamalainen, 1996) showed that lidocaine may also attenuate pain at the brain level.

According to Mao and Chen (2000), the effective dose range of lidocaine (1.5-5.0 mg/kg) is comparable among different neuropathic pain conditions. The onset and peak action of systemic lidocaine vary notably as explained in the literature. There is no consensus about the duration of observation required to see the impact of lidocaine infusion on pain. Studies have reported contradictory results regarding the duration of the analgesic effect of systemic lidocaine (Attal et al., 2000). Some suggest that large residual effects do not occur (Galer et al., 1993) while others suggested effects lasting up to 20 weeks in patients with central neuropathic pain (Backonja & Gombar., 1992).

Lidocaine infusion is one of many therapeutic interventions used in pain clinics. Literature that could help to better identify the patients most likely to benefit from lidocaine infusions has mainly focused on neuropathic pain, as the number one type of pain that can benefit from lidocaine infusions. Attal, Rouaud, and Brasseur (2004) found that response to systemic lidocaine in patients with peripheral neuropathic pain was positively associated with the severity of mechanical allodynia and the degree of sensory impairment. Another cohort study was conducted by Carroll et al. (2007) on 99 patients with suspected neuropathic pain in order to identify clinical characteristics that may contribute to predicting an increased likelihood of a clinically meaningful pain relief with intravenous lidocaine. They found that advancing age and higher pain severity significantly increased the odds of being a lidocaine responder. More specifically, "each decade of advancing age increase the odds of being a lidocaine responder by 36% [and] each 1-point increase in baseline pain severity as assessed by NRS [numerical rating score] increase the odds of being a lidocaine responder by 29%" (p. 705).

However, clinicians frequently comment that patients with other types of pain report decreased pain intensity after a lidocaine infusion. Thus, a policy of inclusion of a variety of pain conditions should determine the study population in order to accurately document these accounts. It is interesting to mention that lidocaine is also used topically

and its efficacy has been shown for various pain conditions such as peripheral neuropathic pain syndromes (Meier et al., 2003). Other studies (Lynch, Clark, Sawynok, and Sullivan, 2005), found that pain intensity was reduced with similar treatments (topical 2% amitriptyline/1% ketamine cream).

Keeping in mind that pain clinics aim to improve patient's level of functioning in addition to reducing pain intensity (Jovey, 2002), it becomes essential to study the impact on function of a lidocaine infusion and to investigate whether beliefs and attitudes towards pain are associated with the lidocaine infusion efficacy and if they change when a lidocaine infusion decreases pain intensity. As well, it may be important to determine which specific beliefs are best associated with reduction of pain with lidocaine infusion, as this could help health professionals to target individuals who might be best served by this intervention.

3. STATEMENT OF HYPOTHESES

3.1 Question

1) Among people with chronic pain who received a first LI, do the responders differ from the non-responders, and 2) do first time LI users differ from the repeat LI users, regarding a) changes in their functional status, b) changes in beliefs and attitudes towards pain, and c) their baseline profile for beliefs and attitudes towards pain?

3.2 Objectives

The main objective is to explore the associations between changes in pain intensity, function, and beliefs and attitudes towards pain for patients who receive a LI. We aim to investigate whether pain intensity decrease on the fourth day post LI and being a first time or repeat LI user impact on those associations. A second objective is to estimate the sample size required for a larger study that would answer the same question. It is important to note that neither the efficacy nor the effectiveness of the treatment are specifically is assessed here.

3.3 Hypotheses

Among people with chronic pain who received a LI,

- The responders, in comparison to the non-responders, a) will report a significantly greater increase in functional status two to three weeks post-infusion, b) will show significantly greater changes in at least one of the beliefs and attitudes towards pain subscales two to three weeks post-infusion and, c) will present a significantly different baseline profile for beliefs and attitudes towards pain.
- The first time LI users, in comparison to repeat LI users, a) will have greater improvement in their functional status two to three weeks post-infusion, b) will show different changes in beliefs and attitudes towards pain, and c) will present a different baseline profile for beliefs and attitudes towards pain.

4. RESEARCH DESIGN

An exploratory study is undertaken to investigate associations between changes in pain intensity, function and beliefs and attitudes towards pain in people with chronic pain who received a LI.

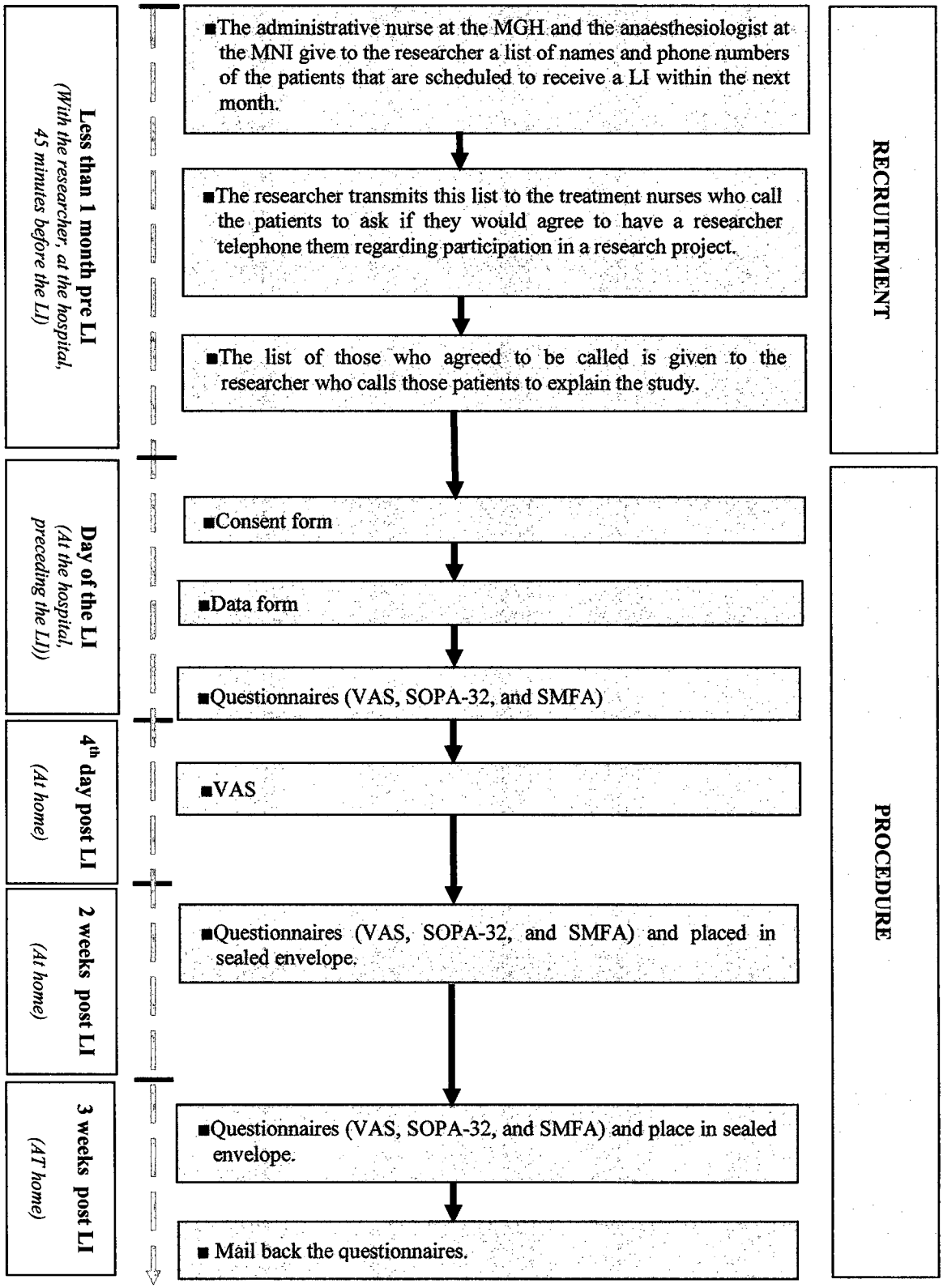
5. METHODS AND PROCEDURES

5.1 Subjects recruitment

A total of 38 subjects were recruited from the MUHC Pain Centre at the Montreal General Hospital (MGH) and the Montreal Neurological Hospital (MNH). Thirty three subjects completed the study. Figure 1 summarizes the recruitment procedure and the steps of this study. On a monthly basis, the administrative nurse at the MGH and the anaesthesiologist at the MNH gave the researcher a list of names and phone numbers of the patients that were scheduled to receive a lidocaine infusion. The researcher subsequently transmitted this list to the treatment nurses who called the patients to ask if they would agree to have a researcher telephone them regarding participation in a research project that used questionnaires to investigate the associations between pain, function, and beliefs and attitudes towards pain following a LI. The list of names and phone numbers of those who agreed to be called were then given to the researcher who called those patients to explain the study and ask if they would agree to fill out a Visual Analogue Scale for pain 4 days post-infusion and answer questionnaires at three time periods: prior to the lidocaine infusion, 2 weeks post-infusion, and 3 weeks post-infusion.

These time periods are based on the clinical observations at the MUHC Pain Centre that 1) around 75% of patients that received LI report a decrease in pain intensity, 2) this relief is most obvious on the fourth day post-infusion, and that 3) the analgesic effect of LI is sometimes diminished two weeks later and does not always persist at three weeks post-infusion.

Figure 1. Timeline diagram



5.2 Inclusion criteria

The inclusion criteria are the following: a) having chronic pain for a minimum of three month's duration, b) receiving a LI for the pain, and c) being able to read and speak English or French, while ethnicity is not a selection criterion. Patients with all types of chronic pain problems, including fibromyalgia, were included, as fibromyalgia patients have very similar characteristics to patients with general musculoskeletal pain (LaChapelle et al., 2005). Patients receiving other treatments than LI were not excluded (Appendix 1). Information about depression was neither clearly nor systematically available in the medical files. Therefore, this aspect was not considered in this study.

5.3 Exclusion criteria

The exclusion criteria were as follows: a) incompletion of the LI, b) expected medication change during the time period of the study, and c) expected to begin a new treatment during the time period of the study. It was thought that these might introduce a selection bias. Reception of an incomplete dose of lidocaine might result in a smaller decrease in pain intensity, therefore weakening the associations between pain, function and attitudes towards pain. Changing medication type or dosage during the study was considered to be very unlikely because they are asked not to do so until their next appointment with their physician in order to see the specific effect of this procedure. However, it was felt that this possibility should also be considered because pain relief due to a new medication, for example, could amplify pain decrease and impact on the associations of interest. As well, starting rehabilitation treatments addressing specific functional difficulties, for example, could improve function during the time period of the study and alter our findings.

5.4 Procedure

As shown in Figure 1, the researcher met the subjects who were willing to participate in the study on the day of the infusion. They met 45 minutes before the infusion either at the MGH or at the MNH. At this time, subjects were given a copy of the consent form to read together with the contact information of the researcher. The

researcher answered any questions regarding the study and those individuals who were still interested in participating in the study signed the consent form. Subjects signed consent the day of the infusion because subject selection occurred at that time. To ensure that the study candidate met the inclusion/exclusion criteria, socio-demographic and clinical characteristics were then collected on a data form by the researcher who interviewed the subject and consulted the medical chart. If the subjects did not meet the inclusion criteria, they were thanked for their time and not asked to continue in the study. Each data form that was retained was placed into an individual and coded anonymous file.

Subsequent to the recruitment and interview procedure, those subjects who fulfilled the inclusion criteria filled out a battery of questionnaires including the Visual Analogue Scale (VAS) for pain (coded to preserve anonymity), with the assistance of the research evaluator. The anonymously completed questionnaires were placed in an appropriate numbered folder. LI were given in private at the MGH and at the MNH after the 45 minutes meeting with the research evaluator. This procedure included the installation of a heart rate and blood pressure monitor and intravenous drip system by the nurse on the subject. The lidocaine infusion was started by the physician with a 1mg per kilo of weight bolus and completed by the nurse with a 4 mg per kilo of weight in a 100 ml of normal saline bag via a pump over one hour. Heart rate, blood pressure and side effects were monitored and managed by the nurse during the infusion. After the infusion, the nurse removed the intravenous drip and the subject was observed but not monitored for 30 minutes by the nurse in the intervention room. The subject was discharged home if vital signs were stable after this period. As part of the routine procedure, subjects were obliged to be escorted by a relative after the infusion and to be seen in a follow up visit 3 to 4 weeks following the infusion.

If the subjects completed the entire infusion, the researcher then gave them a package of questionnaires and pre-addressed stamped envelopes organized into three bundles: VAS alone (for the fourth day), and the VAS plus the questionnaire battery for days 14 and 21. The procedure for filling these out and mailing them back to the researcher was again explained to the subjects to make sure they understood the

instructions. As well, the researcher called each subject on the scheduled dates to remind them to complete the questionnaires on time and to mail them back. All subjects completed the infusion, and so none were rejected for that exclusion criterion. However, 5 patients failed to complete the entire study.

5.5 Exposure

Appendix 1 defines the variables and describes the measurement strategy. The first independent variable is a decrease or no decrease in pain intensity four days after the LI. The VAS for pain was used to measure whether or not there was a decrease in pain intensity on the fourth day post-infusion. The VAS is highly reliable and valid for measuring pain (Finch, Brooks, Stratford, and Mayo, 2002). A 100 mm straight horizontal line anchored at one end by "no pain" and the other end by "the worst pain imaginable" was used. The subjects were asked to mark the line to indicate their pain intensity. For each measurement period, the distance between the "no pain" anchor to the mark placed by the subject is measured. The minimal detectable change for pain intensity on a VAS is ± 28 mm (Finch et al., 2002). However, there is no consensus about the clinically meaningful change on a VAS. Jensen, Chen, & Bruger (2003) suggest that "a 33% decrease in pain represents a reasonable standard for determining that a change in pain is meaningful from the patient's perspective" (p. 407). Klooster Drossaers–Bakker, Taal, & van de Laar (2006) suggest that "patient-perceived satisfactory improvement was associated with a minimal reduction of 30 mm or 55% on the VAS-PI. Since absolute change in pain associated with satisfactory improvement proved highly dependent on baseline pain, percent change scores performed better in classifying improved patients" (p. 151). For the purpose of this study, LI responders were defined as having a criterion-based pain intensity decrease four days after the LI if they satisfied either the 28 mm cut off for the minimal detectible change or the 33% decrease for a minimal clinically meaningful change on a 100 mm VAS. We cautiously chose to consider each criterion since we wanted to detect the smallest change possible.

With respect to assessing clinically meaningful change in pain intensity, it is important to mention that other authors studied the 11-point numerical rating scale (NRS)

where 0 = no pain and 10 = worst possible pain. They reported that either an improvement of 2 points, or a reduction of approximately 30% represent a clinically important difference (Rowbotham, 2001; Farrar, Young Jr., LaMoreaux, Werth, & Poole, 2001; Salaffi, Stancati, Silvestri, Ciapetti, & Grassi, 2004). Carroll et al. (2007) also used a NRS and identified lidocaine responders "as those patients with Numerical Rating Score (NRS) reductions of 30% or greater based on the literature defined criteria for meaningful reductions in pain scores" (p. 703). If we would have choosen to use the NRS instead of the VAS, we would have considered this criterion.

The second independent variable was whether or not the subject was a first time or repeat LI user. This information was extracted from the data form completed on the day of the infusion

5.6 Outcome measures

The outcomes targeted by this study are functional status, and beliefs and attitudes towards pain.

5.6.1 Functional status

Functional status was evaluated using the Short Musculoskeletal Function Assessment Questionnaire (SMFA). The 101-item Musculoskeletal Function Assessment Questionnaire (Tait, Chibnall, & Krause, 1990) was first developed to measure functional status of patients with musculoskeletal disorders that are commonly seen in community practices.

The shortened version (SMFA) takes about ten minutes to complete. It was developed to be used in clinical settings and contains two parts: the Dysfunction Index and the Bother Index. The Dysfunction Index includes 34 items for the assessment of the patients' perception of their functional performance that are grouped into four categories: daily activities, emotional status, function of the arm and hand, and mobility (Tait et al., 1990). A five-point scale is used for each item: 25 items assess the amount of difficulty performing certain activities (1 means *not at all difficult* and 5 means *unable to do*), and the nine other items assess how often the patients have difficulty while performing certain

activities (1 means *none of the time* and 5 means *all of the time*). The Bother Index has 12 items that measure how much patients are bothered by functional problems. These items are ranked on another five-point scale (1 point means *not at all bothered* and 5 means *extremely bothered*). The scores on each index are calculated by transforming the sum of the responses so that they range between 0 and 100 using this formula: ([actual raw score – lowest possible raw score]/possible range of raw score) x 100. At least half of the items of each category of the Dysfunction Index need to be answered to calculate a summary score. Unanswered items can, in those cases, be replaced by the individual's mean score for that category. Score substitution is not possible for the Bother Index in which each item addresses a specific functional area. The higher the score, the poorer is the level of function. Normative data has been collected on a normal population (personal communication, Agel J, September, 2008). However, the minimal clinically significant change has not been determined with this tool (Barei, Agel, & Swiontkowski, 2007). Therefore, a change of at least half the baseline score standard deviation will be considered a meaningful change with this tool as this is one method that can be used to determine the clinical significance of change in health status measures studies (Walters & Brazier, 2003; Puhan, Frey, Büchi, and Schünemann, 2008; Guyatt et al., 2002). As well, no clinical interpretation of the scores has been suggested by the authors of this instrument (Barei et al., 2007).

According to Swiontkowski, Engelberg, Martin, and Agel (1999), the SMFA shows excellent reliability. Stability, as measured by the intraclass correlation coefficients, is 0.93 for the Dysfunction Index. Internal consistency of this Index, measured by Cronbach's alpha values for baseline and follow-up data, is 0.95 and 0.96 respectively. Content validity for the Dysfunction Index displayed good score range (0 to 87 points), distribution with little skew (0.70), no floor effects and few ceiling effects (0.5%). Convergent construct validity was supported with significant correlations between the SMFA Dysfunction Index and the physicians' ratings of patient function and standard clinical measures. Discriminant construct validity was supported and responsiveness to change over time was demonstrated with standardized response means ranging from moderate to large for patients with changes in health status. The French

version of the SMFA has been validated in Québec but this information has not been published yet (personal communication, Agel J, September, 2008).

5.6.2 Beliefs and attitudes towards pain

The Survey of Pain Attitudes (SOPA) measures beliefs and attitudes towards pain. This self-administered questionnaire of 57 items includes seven categories of beliefs and attitudes concerning pain that are considered critical for the adjustment to long term chronic pain. It measures the extent to which the persons believe 1) they can control their pain (Control), 2) they are disabled by their pain (Disability), 3) that pain means they are damaging themselves and that they should avoid exercise (Harm), 4) that their emotions impact their experience of pain (Emotion), 5) that medications are an appropriate treatment for chronic pain (Medication), 6) that others, especially family members, should be solicitous in response to their experience of pain (Solicitude) and, 7) in a Medical Cure for their pain problem (Medical Cure). The respondants are asked to rate their level of agreement with each statement on a 5-point Likert scale from 0 (*this very untrue for me*) to 4 (*this is very true for me*). Each subscale of this tool is related to a specific construct (i.e. underlying beliefs and attitudes towards pain) and the final score for each subscale is the average of all answers in this category. The score of each subscale has to be analysed separately as a measure of overall agreement with the belief construct. Table 1 summarizes the interpretation of the scores for each subscale.

The original SOPA shows good internal consistency (0.71 to 0.81) and test-retest reliability (0.63 to 0.68) (Jensen et al., 1994). Associations between specific SOPA subscales and pain-related measures have been found and support the construct validity of the SOPA (Jensen et al., 2000). Duquette, McKinley, and Litowski (2001) translated and adapted the SOPA for the francophone community in Québec; it became the *Questionnaire sur les Attitudes envers la Douleur (QAD/F-SOPA).* They found that *test-retest coefficients were high for all the subscales except for that of Disability, for which reliability is considered as moderate* (Duquette, McKinley, & Litowski, 2005) and that the majority of the QAD/F-SOPA subscales showed very satisfactory internal consistency whereas the Harm and Disability subscales were close to the satisfactory level.

Table 1. Clinical meaning of the score on each subscales of the SOPA-32.

SOPA- 32 subscales	Score : 0-1	Score : 2	Score : 3-4
Control	The person *does not believe at all* (0) or *does not believe much* (1) that he can control his pain.	The person believes this is *neither true nor untrue* for him or it *does not apply* to him.	The person *believes somewhat* (3) or *a lot* (4) that he can control his pain.
Disability	The person *does not believe at all* (0) or *does not believe much* (1) that he is disabled by his pain.	The person believes this is *neither true nor untrue* for him or it *does not apply* to him.	The person *believes somewhat* (3) or *a lot* (4) that he is disabled by his pain.
Harm	The person *does not believe at all* (0) or *does not believe much* (1) that he should avoid exercise.	The person believes this is *neither true nor untrue* for him or it *does not apply* to him.	The person *believes somewhat* (3) or *a lot* (4) that he should avoid exercise.
Emotion	The person *does not believe at all* (0) or *does not believe much* (1) that his emotions impact his experience of pain.	The person believes this is *neither true nor untrue* for him or it *does not apply* to him.	The person *believes somewhat* (3) or *a lot* (4) that his emotions impact on his experience of pain.
Medication	The person *does not believe at all* (0) or *does not believe much* (1) that medications are an appropriate treatment for chronic pain.	The person believes this is *neither true nor untrue* for him or it *does not apply* to him.	The person *believes somewhat* (3) or *a lot* (4) that medications are an appropriate treatment for chronic pain.
Solicitude	The person *does not believe at all* (0) or *does not believe much* (1) that others, especially family members, should be solicitous in response to his experience of pain.	The person believes this is *neither true nor untrue* for him or it *does not apply* to him.	The person *believes somewhat* (3) or *a lot* (4) that others, especially family members, should be solicitous in response to his experience of pain.
Medical Cure	The person *does not believe at all* (0) or *does not believe much* (1) in a Medical Cure for his pain problem.	The person believes this is *neither true nor untrue* for him or it *does not apply* to him.	The person *believes somewhat* (3) or *a lot* (4) in a Medical Cure for his pain problem.

Associations between specific SOPA subscales and pain-related measures have been found and support the construct validity of the SOPA. According to Jensen et al. (2000), the SOPA Control subscale is associated negatively with measures of dysfunction (depression and disability) and with a *passive style of pain management* (physician visits for pain, pain-contingent medication use, guarding, resting, and asking for assistance) whereas it is associated positively with a *self-management orientation* (relaxation, task persistence, exercise and stretch, and coping self-statement). Considering the SOPA interpretation grid (Table 2) the patients who tend not to believe that they 'can control her pain', also tend to have lower function and to adopt primarily passive pain coping

strategies. Jensen et al. (2000) also found opposite patterns of associations between Disability, Harm and Solicitude subscales and the same measures; lower function and more passive pain coping strategies are associated with stronger beliefs that 'they are disabled by their pain', that 'pain means they are damaging themselves and that they should avoid exercise' and that 'others, especially family members, should be solicitous in response to their experience of pain'. Moreover, depression is associated with stronger belief that 'their emotions impact their experience of pain'. As well, the Medication subscale was positively associated with opioid medication use, whereas the opposite pattern of association was found for the Medical Cure subscale. In other words, a higher belief in medication and a lower belief in Medical Cure were associated with the use of more opioid medications.

Shortened versions of this tool have been developed because clinicians felt that the 57-item original version was too long to administer and to interpret (Tait & Chibnall, 1997; Jensen et al., 2000). For that purpose, the SOPA-B was first developed (Tait & Chibnall, 1997); its subscales reliabilities are generally acceptable (0.70 to 0.83) except for the Medication scale which has a relatively low coefficient of 0.56. All subscales possess adequate internal consistency, with the exception of the Medication subscale. Concurrent validity with the 57-item SOPA is strong (0.79 to 0.97). To meet clinicians' needs in clinical assessments, two additional items from the SOPA-57 were then retained on the SOPA-B questionnaire, with the caveat that they were to be used for clinical assessment purposes only and should not be included in the scoring. In particular, researchers have been advised that they should not include these two items when using this tool, which is called the SOPA-32, for research purposes (Duquette, McKinley, Jacques, Oléa, & Tapin, 2006).

The French version of the SOPA-32 is based on the corresponding terms of the QAD/F-SOPA; it is called the *Questionnaire sur les attitudes envers la douleur / version abrégée* (QAD/F-SOPA-32). The QAD/F-SOPA-32 shows satisfactory test-retest reliability; Pearson r values are greater than 0.7 for six of the seven subscales. Internal consistency also appears very satisfactory; the Cronbach's alpha values are between 0.7 and 0.9 for six of the seven subscales (Duquette et al., 2006). The SOPA-32 takes about

12 minutes to complete. We chose to use this short version knowing that individuals with chronic pain problems often have difficulty concentrating.

Statistical significance of the changes in the scores of each SOPA-32 subscale is considered in this study. However, a change of at least half the baseline score standard deviation is considered a meaningful change (Walter & Brazier, 2003; Puhan et al., 2008; Guyatt et al., 2002) whether or not this change is statistically significant. We were interested in looking at the trends of the changes for each belief. In other words, a change of at least half a standard deviation reveals a meaningful tendency in their beliefs to increase or decrease, independently if they change category on the interpretation grid or not. Decimals are not kept; 1.05 and 1.95 will be, for example, considered as a 1 (Jensen MP, personal communication, September 2008) on the SOPA-32 ordinal subscales.

5.7 Potential confounders

Potential confounders are variables that may bias the associations between pain intensity, function and beliefs and attitudes towards pain. Thus, the 13 potential confounding variables considered in this study are listed in Appendix 1. This information was extracted from the data form completed on the day of the infusion.

5.7.1 Socio-demographic variables

5.7.1.1 Age

Age may impact on the way people perceive and/or report pain intensity. In a Canadian survey (Moulin et al., 2002), younger patients experienced significantly more pain than did older patients. Tait et al. (1990) found that older patients report less disability than younger patients. This variable is also considered in studies using the SOPA (Jensen et al., 1999). Also, advancing age has been showed to be associated with analgesic response to intravenous lidocaine (Carroll et al., 2007).

5.7.1.2 Gender

Pain perception differs between men and women (Unruh, 1996) and many hypotheses have been proposed to explain this difference. The extent to which lidocaine changes pain intensity may also differ. In a sample where female subjects would

outnumber male subjects, if females report a higher rate of decreased pain intensity and similar changes in functional status and beliefs and attitudes towards pain, the association between pain intensity and these outcomes will be overestimated. As well, some studies (Arnstein et al., 1999; Tait et al., 1990; Lamé et al., 2005; Keefe et al., 2000) found different disability levels between men and women.

5.7.1.3 Education level

Tait et al. (1990) found a negative correlation between disability using the Pain Disability Index and education level. In their study, more educated patients were less restricted by pain perhaps as a result of the type of occupation they are involved in before pain occurred.

5.7.1.4 Marital status

This variable was taken into account in studies using the SOPA (Jensen et al., 1999). This element of social support may impact on the way the person perceives him or herself as being disabled and her beliefs and attitudes towards pain.

5.7.1.5 Employment status

Arnstein et al. (1999) found higher disability scores for subjects not currently working and this variable was taken into account into studies using the SOPA.

5.7.1.6 Compensation status

This variable account for around 7% of the variance of disability levels in pain patients in a study where the Pain Disability Index was used (Chibnall & Tait, 1994). Arnstein et al. (1999) found higher disability scores using this tool for subjects receiving disability income.

5.7.2 Pain-related variables

5.7.2.1 Pain intensity

A stronger association has been found between function and SOPA scores for patients with lower pain intensity (Jensen et al., 1999) than those with higher pain intensity. Also, a positive correlation has been found between pain intensity and the odds of being a lidocaine responder (Carroll et al., 2007). Therefore, pain intensity measured

before the lidocaine infusion (during the pre-infusion meeting) will be considered as a potential confounder.

5.7.2.2 Duration of pain

Subjects who have pain for a longer period of time may present with an important physical deconditioning and have more negative attitudes towards their persisting pain. Strong relationships have been found between specific beliefs and function for patients with shorter pain duration (Jensen et al., 1999). As well, Tait et al. (1990) found a negative correlation between disability and pain duration, suggesting that people may accommodate to pain as it persists. Therefore, the association between decrease in pain and these outcomes may be partly modulated by pain duration.

5.7.2.3 Localization of pain and number of painful sites

This variable may induce a selection bias. Decrease in pain intensity may induce more important and faster changes in attitudes towards pain at the upper extremity because the subjects may find it more satisfying to use their arms more easily than to walk longer, for example. Since it is not feasible in terms of time to include enough subjects that would present the same pain localisation, this characteristic has to be analysed as a confounding variable. According to Chibnall and Tait (1994), "different types of pain patients may report varying levels of disability... [and] it seems that low back pain patients report slightly more disability than patients with upper extremity pain" (p. 1085). Arnstein et al. (1999) and Lamé et al. (2005) found higher disability scores for specific locations of pain.

5.7.2.4 Circumstance of pain onset

Chibnall and Tait (1994) reported that "patients who were injured at work reported more disability than those whose pain began after a non-work accident or illness/surgery and those whose pain had no identifiable cause" (p. 1082). This variable can have an impact on the associations between pain intensity, function and beliefs and attitudes towards pain.

5.7.2.5 Use of opioids

It has been shown that the use of opioids does not impact on the functional outcomes after pain rehabilitation programs (Rome et al., 2004; MacLaren, Gross, Sperry, and Boggess, 2006). Carroll et al. (2007) found that previous trials of opioids did not predict the likelihood of having an analgesic response to intravenous lidocaine. However, no study specifically addressed the efficacy of lidocaine infusions in conjunction with the use of opioids. Considering this aspect in this study is novel and might lead to interesting observations.

5.7.2.6 Current treatments

Co-interventions may enhance the association between decrease in pain intensity, function and attitudes towards pain. Successful psychology treatments targeting anxiety and depression, for example, might lead to decrease pain perception (Sullivan, Reesor, Mikail, & Fisher, 1992) and/or disability (Keogh, McCracken, & Eccleston, 2006). Therefore, if one group includes more subjects who had their mood improved during this research, results could be biased.

5.8 Other variables

These characteristics will be considered in secondary analyses and collected via the same data form.

5.8.1 Category of pain

Because the effect of lidocaine may differ for patients with different pain conditions (Attal et al., 2000; Galer et al., 1993), this variable may impact on the associations between pain intensity, function and beliefs and attitudes towards pain.

5.8.2 Presence of mechanical allodynia

Lidocaine infusion may have different impact on different signs and symptoms (Attal et al., 2000) and a study (Attal et al., 2004) found that the severity of mechanical allodynia increased the odds of being a lidocaine responder. If subjects having signs and symptoms that are poorly relieved by lidocaine infusion represent a large proportion of

the sample, it may weaken the associations between pain intensity, function and beliefs and attitudes towards pain.

5.8.3 Number and length of LI

It might be interesting to consider the number and length of LI in order to explore if the frequency and time period of this intervention intervenes in its success and impacts on the associations between pain intensity, function and beliefs and attitudes towards pain. No study has explored this aspect before.

5.9 Sample size

Because this is an exploratory study and there are no specific data using these outcome measures for this population, we decided that we would recruit every subject who would undergo a LI at the MGH or the MNH, and who would sign consent, during a seven months period. Therefore, no sample size calculation was done at that point.

5.10 Statistical analysis

Generalized linear models (GZLM) and generalized estimating equations (GEE) approaches were used. Generalized linear models cover not only widely used statistical models, such as linear regression for normally distributed responses, logistic models for binary data, and log linear model for count data, but also many useful statistical models via its very general model formulation (SPSS user's manual). However, the independence assumption prohibits application of generalized linear models to correlated data. Generalized estimating equations were developed to extend generalized linear models to accommodate correlated longitudinal data and clustered data. More particularly, generalized estimating equations model correlations within subjects. Data across subjects are still assumed independent. The GEE algorithm does not allow for sequential inclusion of variables in the model. Therefore, all confounders and independent variables were entered together if the frequency of categories allowed for it.

In this study, the dependent variables were the values of the SOPA-32 subscales or SMFA Indexes that indicated the largest difference with the pre-infusion values (at either

the 2nd or 3rd weeks post-infusion). We used the pre-infusion value for the corresponding scale as an offset variable. The offset term is a "structural" predictor. Its coefficient is not estimated by the model but the values that are used are the differences between the dependent variable and the offset variable. The confounding variables used were the same. The simple main effects model was used. The level of significance for each GEE analysis was set at $p < 0.05$, not controlling for multiplicity of tests, except in the post-hoc pair-wise comparisons where a sequential Bonferroni correction was applied. Estimated marginal means were calculated in order to give an idea of the mean when controlling for the confounding variables. Since the three groups of this exploratory study were small, differences were controlled so that baseline characteristics would not impact the associations of interest.

The third objective was to explore baseline characteristics (functional or attitudinal) that could be associated with a decrease in pain. Considering the small number of subjects, simple bivariate associations between the decrease in pain and the baseline characteristics were done as well as a forward conditional logistic regression using baseline variables that were marginally associated with a decrease in pain ($p < 0.10$ according to the bivariate association). The logistic regression was done in order to determine if a decrease in pain was explained in part by baseline profiles and if so, how much (percentage of variation determined by baseline characteristics). This analysis was exploratory in nature and the level of significance for the logistic regression was set at $p < 0.10$.

Secondary analyses compared the three groups' profiles (baseline characteristics and dependent variables) at baseline, on the fourth day post-infusion (VAS) and post-infusion (VAS, SOPA-32, and SMFA). We used one-way ANOVAs for numeric variables and chi-square statistics for categorical variables. To compensate for the multiplicity of tests, we used a level of significance of $p < 0.01$.

A double entry of data was performed on Excel datasheet. The first entry was done by the evaluator and the second entry by a research assistant. The two files were validated to eliminate data entry errors. Then, the Excel datasheet was transferred to SPSS by an automated process for analysis.

6. RESULTS

6.1 Baseline Characteristics According To Group Allocation

6.1.1 Group allocation

Of the 38 subjects that were recruited, no subject refused to participate in the study, everyone completed the infusion, and 33 completed the study. As none of the first time LI users had a criterion-based pain intensity decrease, the subjects were separated into three groups depending on whether or not they had: a) criterion-based pain intensity decrease on the fourth day post-infusion, and b) received a previous LI. The three groups that emerged from this classification are as follows and described in Table 2: group 1 ($n = 9$), first time LI users with no pain decrease; group 2 ($n = 16$), repeat LI users who did not report pain decrease; group 3 ($n = 8$) repeat LI users who did report pain decrease.

6.1.2 Baseline profiles, confounding variables

Table 2 includes the baseline (pre-infusion) characteristics of the three groups. One-way ANOVAs for numerical variables and chi-square statistics for categorical variables showed that these three groups were comparable regarding their baseline characteristics ($p < 0.01$). Interestingly, group 3 had higher, but not significant ($F = 2.508$, $p = 0.098$), pain intensity than the other two groups. The pain intensity means and standard deviations respectively for groups 1-3 were 49.67 ± 8.44, 50.38 ± 11.70 and 80.75 ± 14.81.

Mean age varied between 49 and 53 years old (50 years 10 months ± 6 years and 1 month), and the majority of the subjects were married women (91%; $n = 30$), with an education above high school level (67%; $n = 22$), who were not working because of their pain problem (64%; $n = 21$) and who were receiving a disability income (67%; $n = 22$). Their pain problem appeared, on average, between seven to ten years ago (eight years and one month ± 1 month). Most of the subjects reported pain localized at more than three sites of their body (61%; $n = 20$). Interestingly, a close to significant difference ($p = 0.027$) appeared for group 3 subjects in that they all reported pain in the head region,

Table 2. Baseline values, confounding variables.

	Group 1 (n = 9) First time LI users, no pain decrease	**Group 2** (n = 16) Repeat LI users, no pain decrease	**Group 3** (n = 8) Repeat LI users, pain decrease
Socio-demographic confounders			
Age			
mean ± SD	49.67 ± 8.441	50.38 ± 11.701	53.13 ± 6.468
median	47.00	48.50	53.50
Gender			
%female	77.8	62.5	100.0
Education level			
%higher than high school	77.8	56.3	75.0
Marital status			
%married	100.0	81.3	100.0
Employment status			
%working	22.2	12.5	12.5
%no, because of pain	66.7	56.3	75.0
%no, other reason	11.1	31.3	12.5
Compensation status			
%with disability income	55.6	62.5	87.5
Pain-related confounders			
Pain intensity (pre LI)			
mean ± SD	59.11 ± 25.73	58.0 ± 27.47	80.75 ±14.81
median	57.00	62.50	81.00
Duration of pain			
mean ± SD	87.44 ± 95.913	91.06 ± 60.559	121.63 ± 72.693
median	48.00	82.00	110.00
Localization of pain			
%head	55.6	43.8	100.0 ~ : *p= 0.027*
%neck	66.7	75.0	75.0
%upper extremity	66.7	75.0	62.5
%back	55.6	56.3	50.0
%lower extremity	77.8	68.8	50.0
Number of painful sites			
%more than 3 sites	55.6	68.8	100.0
Circumstance of pain onset			
%accident	33.3	56.3	25.0
%illness	55.6	37.5	62.5
%other	11.1	6.3	12.5
Use of opioids			
%yes	44.4	68.8	87.5
Current treatments			
%medication	88.9	93.8	100.0
%blocks	0	6.0	0
%psychology	22.2	25.0	12.5
%physiotherapy	22.2	25.0	12.5
%modalities	33.3	6.3 ~ :*p = 0.047*	50.0
%osteopathy	33.3	12.5	0

~: *borderline difference between the groups.*

whereas the other groups did not (56%; n = 18, and 44%; n = 15 for groups 1 and 2 respectively). While the majority of the subjects were taking opioids for their pain problem, the percentage of users increased from group 1 to group 3 (44%; n = 15, 69%; n = 23, and 88%; n = 29 respectively), although this difference did not reach significance. In each group, less than a third were receiving nerve or venous blocks, individual psychology counselling, support group, education, physiotherapy, osteopathy, acupuncture and/or massotherapy treatments. A close to significant difference (p = 0.047) appeared for group 2 subjects for use of modalities such as radiofrequency, TENS or neurostimulator as they are receiving less than the two other groups (6%; n = 1 for group 2 vs. 33%; n = 11, and 50%; n = 17 for groups 1 and 3 respectively). Although not statistically significant, this group also differed from the other two groups in that the majority of them reported that their pain problem appeared after an accident rather than from an illness (56%; n = 18 for group 2 vs. 33%; n = 11, and 25%; n = 8 for groups 1 and 3 respectively).

6.1.3 Baseline profiles, non-confounding variables

In Table 3, those variables that were not considered as confounders in this study are listed. Mechanical allodynia is present for half the subjects in group 1 (55%; n = 5) and group 3 (50%; n = 4). The proportion of group 1 subjects who had nociceptive pain (44%; n = 4), neuropathic pain (44%; n = 4) and combined pain (11%; n = 1) is also similar to group 3 (nociceptive pain 38%; n = 3; neuropathic pain 50%; n = 4; combined pain 0%). Group 2 differs in that only one subject had mechanical allodynia (6%) and that the category of pain is differently distributed (nociceptive pain 44%; n = 7; neuropathic pain 19%; n = 3; combined pain 25%; n = 4). Group 2 subjects received, on average, eight LI over the past thirteen months whereas group 3 subjects received an average of six LI over the past nineteen months.

Table 3. Baseline values, non-confounding variables.

	Group 1	Group 2	Group 3	Total
	First time LI users, no pain decrease	Repeat LI users, no pain decrease	Repeat LI users, pain decrease	
Category of pain				
Nociceptive	4 (44%)	7 (44%)	3 (38%)	14 (42%)
Neuropathic	4 (44%)	3 (19%)	4 (50%)	11 (33%)
Combined	1 (11%)	4 (25%)	0	5 (15%)
Not specified	0	2 (13%)	1 (13%)	3 (9%)
Signs & symptoms				
M. allodynia	5 (55%)	1 (6%)	4 (50%)	10 (30%)
No m. allodynia	4 (44%)	12 (75%)	3 (38%)	19 (58%)
Not specified	0	3 (19%)	1(13%)	4 (12%)
Number of LI		8	6	
Not specified	0	3	1	N/A
LI length (months)		13	19	
Not specified	N/A	2	0	N/A

m = mechanical

Table 4. Baseline scores (pre-infusion) of the dependent variables.

	Mean scores		
	Group 1	Group 2	Group 3
	First time LI users, no pain decrease	Repeat LI users, no pain decrease	Repeat LI users, pain decrease
SMFA			
Dysfunction	0.52 ± 0.24	0.49 ± 0.19	0.52 ± 0.23
Bother	0.64 ± 0.26	0.60 ± 0.23	0.70 ± 0.25
SOPA-32			
Control	1.91 ± 0.68	2.22 ± 0.61	1.93 ± 0.95
Disability	3.33 ± 0.73	3.03 ± 0.83	3.47 ± 0.71
Harm	2.64 ± 0.88	1.88 ± 1.13	1.50 ± 1.00
Emotion	2.53 ± 1.15	2.48 ± 1.17	2.06 ± 1.36
Medication	2.14 ± 1.18	2.33 ± 1.03	3.29 ± 0.33*
Solicitude	0.87 ± 0.57	1.26 ± 1.24	1.40 ± 0.83
Medical Cure	2.51 ± 0.76	1.93 ± 0.97	2.15 ± 0.59

**: significant difference between the groups; $p < 0.05$*

6.1.4 Baseline values of the dependent variables

With respect to the dependent variables at baseline (Table 4), the level of function and the beliefs and attitudes towards pain for the three groups were comparable, except for the SOPA-32 Medication subscale. Group 3 subjects showed a stronger belief that 'medications are an appropriate treatment for chronic pain' ($p = 0.041$). The three groups were similar at baseline regarding their scores on the other subscales of the SOPA-32.

On the SMFA, their Dysfunction Index scores ranged from 49-52 and their Bother Index scores ranged from 60-70 on a range of 0 to 100. As mentioned before, no clinical interpretation of the scores has been suggested by the authors of this instrument (Barei et al., 2007). However, scores of the normal population are 12.70 ± 15.59 for the Dysfunction Index and 13.77 ± 18.59 for the Bother Index.

6.2 Changes in measurement variables post LI

Table 5 summarizes the following results whereas Table 6 gives the final score for each measurement variable.

6.2.1 Independent variable - Pain intensity (VAS)

Figure 2 shows pain intensity evolution over time for the three groups using the VAS (0 means *no pain* and 100 means *the worst pain imaginable*). Baseline scores were similar between groups 1 (59.11 mm) and 2 (58.00 mm). By day 4, only group 3 subjects showed criterion-based pain intensity decrease going from 80.75 mm to 27.25 mm, for an average decrease of 53.50 mm or 66%. The other two groups had only small reductions in pain intensity (-6.78 mm or -11% for group 1 and -8.29 or -14% for group 2). Looking at the VAS scores at day four, the three groups were not significantly different ($p=0.062$). When considering the maximum decrease recorded between baseline and measurements at either two or three weeks post-infusion, there was no significant difference between the groups ($p = 0.287$) as well. However, while all three groups showed an increase in intensity from day 4 levels, this increase brought the level of pain back to that of pre-infusion for group 1 while for group 2, the average VAS continued to decrease. For group 3, the intensity level increased, but was still 50% below that of pre-infusion levels.

Table 5. Estimated marginal means of the change between pre and post-infusion (at either the 2nd or 3rd week) for each SMFA Index and SOPA-32 subscale.

	Estimated marginal means		
	Group 1	**Group 2**	**Group 3**
	First time LI users, no pain decrease	Repeat LI users, no pain decrease	Repeat LI users, pain decrease
SMFA			
Dysfunction	0.03	0.08	0.03
Bother	0.12	0.17°	0.17°
SOPA-32			
Control	-0.47°	-0.31°	-0.63°
Disability	0.13	0.71°	0.36°
Harm	-0.47°	-0.30	0.68**°
Emotion	0.30	0.68°	0.53
Medication	1.16**Δ°	-0.87**Δ°	0.44**°
Solicitude	0.39Δ°	1.76**Δ°	0.80Δ°
Medical Cure	-0.36	0.59*°	-0.48°

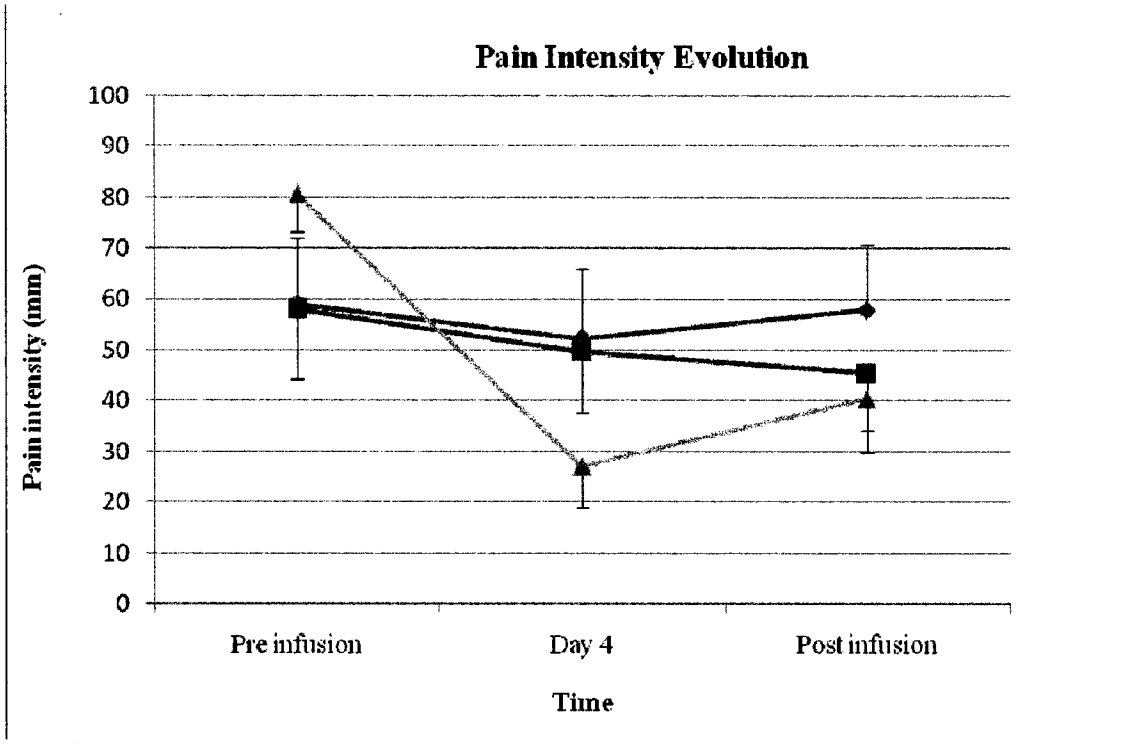
*: *Significant difference in change scores between the groups; $p < 0.05$*
**: *Significant difference in change scores between the groups; $p < 0.001$*
Δ: *Significant change from baseline score; $p \leq 0.001$*
°: *Meaningful change from baseline (≥ ½ SD of the baseline score)*

Table 6. Final scores (maximal change at either the 2nd or 3rd week post-infusion) of the dependent variables.

	Mean scores		
	Group 1	**Group 2**	**Group 3**
	First time LI users, no pain decrease	Repeat LI users, no pain decrease	Repeat LI users, pain decrease
SMFA			
Dysfunction	0.55 ± 0.22	0.57 ± 0.20	0.55 ± 0.31
Bother	0.76 ± 0.22	0.77 ± 0.22	0.87 ± 0.31
SOPA-32			
Control	1.44 ± 0.86	1.91 ± 0.88	1.30 ± 1.00
Disability	3.46 ± 1.02	3.74 ± 1.02	3.83 ± 1.10
Harm	2.17 ± 0.87	1.58 ± 0.68	2.18 ± 1.22**
Emotion	2.83 ± 1.22	3.16 ± 1.26	2.59 ± 1.23
Medication	3.30 ± 0.80**	1.46 ± 0.81**	3.73 ± 1.03**
Solicitude	1.27 ± 0.81	3.02 ± 1.15**	2.20 ± 0.75
Medical Cure	2.15 ± 0.83	2.52 ± 0.88*	1.67 ± 1.02

*: *Significant difference between the groups; $p < 0.05$*
**: *Significant difference between the groups; $p < 0.001$*

Figure 2. Pain intensity evolution.



This figure illustrates pain intensity evolution over time for the three groups Post-infusion changes represent the maximal change recorded at either the 2nd or 3rd week response intervals.
◊: Group 1, error bars are up.
□: Group 2, error bars are down.
Δ: Group 3, error bars are down.

6.2.2 Statistical differences in the dependent variables between and among the three groups

6.2.2.1 Function (SFMA)

There were no significant differences between the groups regarding changes in function from baseline to 2 to 3 weeks post-infusion ($p = 0.535$ for the SMFA Dysfunction Index; $p = 0.370$ for the Bother Index). As well, there were no significant changes in function from baseline for any of the groups; all three groups showed small but non-significant increases in Dysfunction and Bother scores.

6.2.2.2 Beliefs and attitudes towards pain (SOPA-32)

Significant differences were found between the three groups regarding changes in 4 of the 7 subscales of the SOPA-32: Harm, Medication, Medical Cure and Solicitude. For Harm, Medication, and Medical Cure, not only were there significant differences, but the direction of the change was different. a) For Harm, group 3 was significantly different from groups 1 and 2 ($p = 0.000$); and showed an increase in their belief that they should avoid exercise, whereas this belief decreased for groups 1 and 2. b) For Medication, as compared to groups 1 and 3, group 2 showed a significant decrease ($p \leq 0.001$) in their belief that 'medications are an appropriate treatment for chronic pain'; in addition, this belief increased for groups 1 and 3 where it reached significance for group 1 ($p \leq 0.001$). c) For Medical Cure, group 2 was significantly different from groups 1 and 3 ($p = 0.026$) and showed an increase in their belief in a 'Medical Cure for their pain problem' whereas this belief decreased for groups 1 and 3. d) For Solicitude group 2 had a significantly larger increase than the other two groups ($p = 0.000$). e) Also, all groups showed a significant increase ($p \leq 0.001$) in their belief that 'others, especially family members, should be solicitous in response to their experience of pain'.

6.2.3 Meaningful changes in the dependent variables within each group

6.2.3.1 Function (SFMA)

Groups 2 and 3 mean increases (+ 0.17 for both groups) in the Bother score were substantial enough to be considered meaningful, as defined by a change of at least half the baseline score standard deviation (Walters & Brazier, 2003; Puhan et al., 2008; Guyatt et al., 2002).

6.2.3.2 Beliefs and attitudes towards pain (SOPA-32)

Meaningful changes were also group-dependent. While all groups showed a meaningful decrease in their belief that 'they can control their pain' other changes were group specific. Groups 2 and 3 both showed a meaningful increase in their belief that 'they are disabled by their pain', only group 2 had a meaningful increase in the belief that 'their emotions impact their experience of pain' and only group 3 showed a meaningful increase in their belief that 'medications are an appropriate treatment for chronic pain'. For the other changes, two of the three groups showed meaningful changes, but the directions were different. In the belief that they should avoid exercise, group 3 showed a meaningful increase whereas group 1 showed a meaningful decrease. For the belief in a 'Medical Cure for their pain problem', group 2 showed a meaningful increase whereas this belief meaningfully decreased for group 3.

6.2.4 Changes in pain intensity (VAS) with respect to the SOPA changes

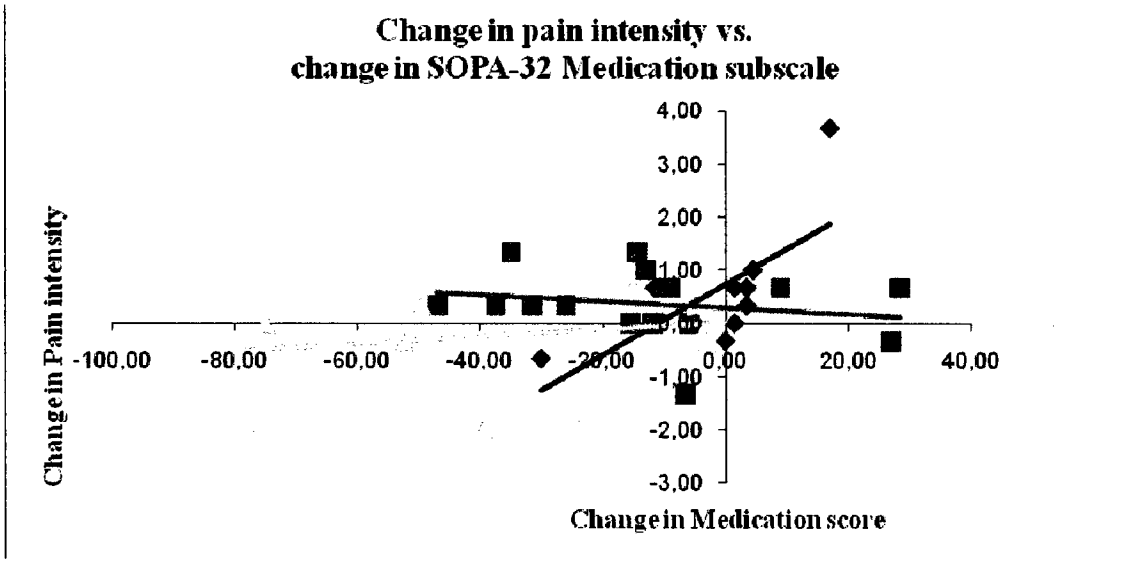
One of the goals of the study was to investigate whether or not baseline profile of beliefs and attitudes towards pain (SOPA-32) were correlated with the change in pain intensity four days post-infusion. With respect to the SOPA-32 Medication and Harm subscales, subjects who reported decrease in pain intensity (group 3) have a different baseline profile than those who don't (groups 1 and 2). The Medication subscale explains 22 to 33% of the variance in predicting the chances of experiencing pain decrease four days after a LI and that this proportion is enhanced to 29 to 43% when the Harm factor is added. In fact, the more a subject believed 'that medications are an appropriate treatment for chronic pain' and the less they believed 'that they should avoid exercise', the higher the chances of experiencing a decrease in pain intensity four days after a LI.

6.3 Secondary analysis

Because of the small sample size in this exploratory study, secondary analyses were performed to further asses the data. Scatter plots were done to see if trends exist for maximal change at either 2 or 3 weeks post-infusion in pain intensity and function, and/or beliefs and attitudes towards pain. Only two significant correlations were found, and both occurred in group 1 (Figures 3 and 4). Although the VAS post-infusion score was, on

average, very similar to the pre-infusion score (-1 mm), it appears that the vast majority of group 1 subjects had increased pain intensity after the LI; a) the smaller the increase in reported pain post-infusion, the less increase was observed in their belief that 'medications are an appropriate treatment for chronic pain' ($p = 0.038$), and b) the less the pain intensity increased after the infusion, the more increased was their belief 'in a Medical Cure for their pain problem' ($p = 0.031$). However, we should be cautious in these interpretations as these correlations are influenced by two extreme cases.

Figure 3. Changes in pain intensity vs. changes in SOPA-32 Medication subscale.



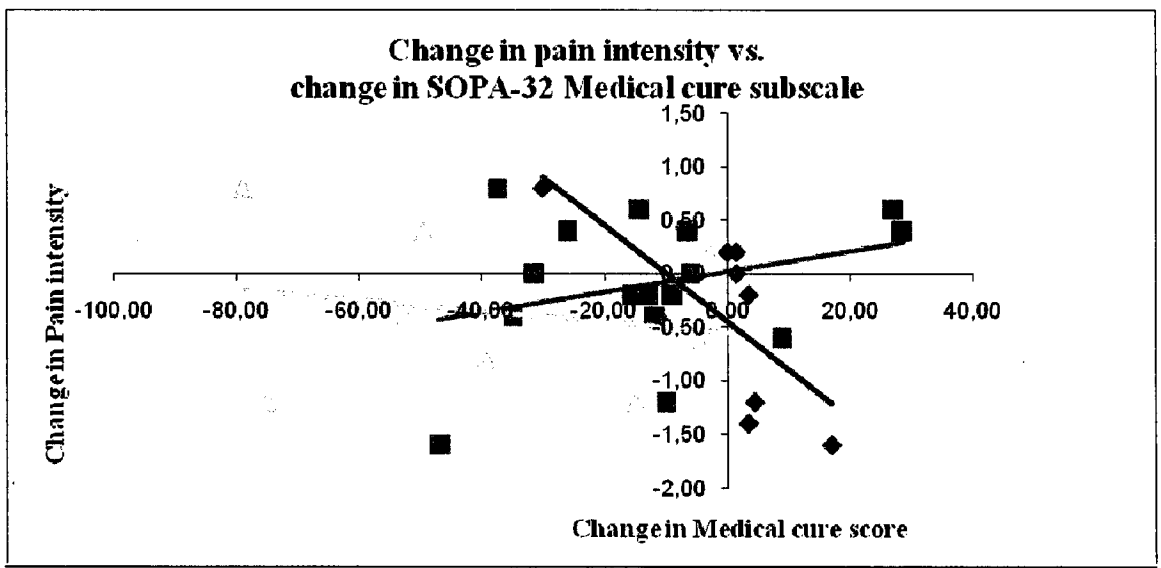
This scatter plots illustrate the individual scores for all subjects in each group for maximal change in both measures (at either the 2nd or 3rd week post-infusion). The lines represent the average trend for each group.

♦ : Group 1, p = 0.038.

■ : Group 2, p = 0.477.

△ : Group 3, p = 0.559.

Figure 4. Changes in pain intensity vs. changes in SOPA-32 Medical Cure subscale.



This scatter plots illustrate the individual scores for all subjects in each group for maximal change in both measures (at either the 2nd or 3rd week post-infusion). The lines represent the average trend for each group.

♦ : Group 1, p = 0.031.

■ : Group 2, p = 0.246.

△ : Group 3, p = 0.631.

6.4 Calculation of the sample size

Calculation of the sample size for future studies that would address the same research question was based on data that was collected in this exploratory study and done in two successive steps. First, the sample size was established to be able to have 80% power to detect an interaction between the groups and the measuring points (4 days, 2 weeks and 3 weeks post-infusion). Then, this sample size was used to determine the power to detect clinically significant differences between the groups and between the measuring points. Those statistical analyses were combined for practical purposes, and revealed that approximately seventy subjects would be required in each of the four groups: first time LI users with pain decrease, first time LI users without pain decrease, repeat LI users with pain decrease, and repeat LI users with no pain decrease.

6.5 Summary of the profiles of the three groups

Table 7 summarises the specificities and changes that have occurred for every outcome variable in each group.

6.5.1 Group 1- first time LI users, no pain decrease

Group 1 subjects had an equal proportion of subjects with nociceptive pain and neuropathic pain, and approximately half of them had allodynia. On the VAS, these subjects had an average of 59 mm pre-infusion, 52 mm four days post infusion and 58mm two to three weeks post-infusion. Therefore, it seems that a small but not criterion-based pain intensity decrease (-7 mm or -12%) briefly occurred four days after their first lidocaine infusion but that pain intensity went back to the baseline level two to three weeks later.

Changes on the function scores were not significant (+3% on the SMFA Dysfunction Index and +12% on the Bother Index) although both increased. However, the Bother Index approached meaningful change as the mean score was increased by 12.27 and, at least 12.96 was required according to our criteria of at least half a standard deviation of the baseline score (Walters & Brazier, 2003; Puhan et al., 2008; Guyat 2002).

However, secondary analyses showed that the more that pain intensity was decreased two to three weeks after the infusion, the less were they bothered by functional problems, compared to before the infusion.

At baseline, this group tended to believe that 'they should avoid exercise' (2.64 ± 0.88) at baseline whereas the other groups were *ambivalent* (1.88 ± 1.13 and 1.50 ± 1.00 for groups 2 and 3 respectively). The changes in the SOPA-32 scores also revealed an interesting portrait of these subjects. After receiving their first lidocaine infusion, these subjects showed a tendency to believe less that 'they can control their pain' and that 'they should avoid exercise'. They also had a significant increase (+1.16, $p \leq 0.001$) in their belief that 'medications are an appropriate treatment for chronic pain'. However, a positive correlation was found between changes in pain intensity and changes in their beliefs in the appropriateness of medications; the smaller the increase in reported pain post-infusion, the less of an increase was observed in their belief that 'medications are an appropriate treatment for chronic pain' and vice-versa.

This group also reported a significant increase (+0.40; $p \leq 0.001$) in their belief that 'others, especially family members, should be solicitous in response to their experience of pain' after their first lidocaine infusion.

6.5.2 Group 2- repeat LI users, no pain decrease

Group 2 subjects received, on average, eight lidocaine infusions during the last thirteen months. In this group, only one subject had allodynia and, although nociceptive pain was predominant, neuropathic and combined pain categories were also represented. On the VAS, these subjects had an average of 58 mm pre LI, 50 mm four days post LI and 46 mm two to three weeks post LI. This decrease of 8 mm (-14%) on the VAS, however, did not meet our criteria. Interestingly, pain intensity was even lower (-12 mm or -21%, compared to pre-infusion) two to three weeks after the infusion. Thus, there was a slight tendency for pain intensity to decrease in time.

At baseline, group 2 showed specific differences from the other two groups although these did not reach the level of significance in this small sample. They were

receiving fewer modalities such as radiofrequency, TENS or neurostimulator ($p = 0.047$) and the majority of them reported that their pain problem appeared after an accident rather than from an illness (56% vs. 33% and 25%, for groups1 and 3 respectively).

Scores of both indices of the SMFA were not significantly increased while controlling for the confounding variables: +8% on the Dysfunction Index and +17% on the Bother scale. However, they showed a tendency to be a little more bothered by functional problems after the infusion while secondary analyses showed that the more that pain intensity was decreased two to three weeks after the infusion, the less were they bothered by functional problems, compared to before the infusion.

Significant changes were reported on two SOPA-32 subscales after the LI. While reporting a small pain intensity decrease, these regular LI users showed a significant decrease in their belief in the appropriateness of medications (-0.87, $p < 0.05$). Concomitantly, they showed a significant increase (+1.76, $p < 0.05$) in their belief that 'others, especially family members, should be solicitous in response to their experience of pain'. In addition to these significant changes, group 2 subjects also showed tendencies to believe more that 'they are disabled by their pain' and that 'their emotions impact their experience of pain'. They also tend to increase their belief 'in a Medical Cure for their pain problem' but slightly decrease their belief that 'they can control their pain'.

6.5.3 Group 3- repeat LI users, pain decrease

Group 3 subjects received, on average, six lidocaine infusions during the last nineteen months. Neuropathic pain and nociceptive pain were similarly represented and half the subjects had allodynia. On the VAS, although not significant ($p = 0.098$), for these subjects, baseline pain intensity was much higher than for the two other groups. This group had a criterion-based decrease in pain intensity four days after the infusion (-54 mm or -67%) and also at two to three weeks post infusion (-40 mm or -49%). Interestingly, their pain was more diffuse since they all had pain in more than 3 sites of their body (compared to 56% in group 1 and 69% in group 2), and they had the longest pain duration (121 months compared to 87 months for group 1, and 91 months for group 2). They were also different in that they all reported pain in the head region whereas the

other groups did not (100% vs. 56% and 44% for groups 1 and 2 respectively) and that they included the highest proportion of users of opioids (88% vs. 44% and 69% for groups 1 and 2 respectively). However, the above differences did not reach statistical significance in this small sample.

Changes on the function scores were not significant (+3% on the SMFA Dysfunction Index and +17% on the SMFA Bother Index). However, they showed a tendency to be a little more bothered by functional problems after the infusion.

The repeat LI users who benefited from this infusion had a significantly higher score ($p < 0.05$) in SOPA-32 Medication subscale at baseline (3.29 ± 0.33) with a small standard deviation. Furthermore, this belief tended to increase after the infusion. As well, group 3 subjects reported a significant increase (+0.80, $p < 0.05$) in their belief that 'others, especially family members, should be solicitous in response to their experience of pain'. They also showed a tendency to increase their beliefs that 'they are disabled by their pain' and that 'they should avoid exercise'. Finally, they tended to believe less that 'they can control their pain' and 'in a Medical Cure for their pain problem' after the LI.

Table 7. Summary Table.

#	Group variables		Specificities in baseline characteristics		VAS		SMFA		SOPA-32						
							Dysfunction	Bother	Control	Disability	Harm	Emotion	Medication	Solicitude	Medical cure
	First LI ?	Pain ↓ ?	Confounders	Non-confounders	D4 – Pre LI	Maximal change	Maximal change (mean ± SE, 2 or 3 weeks post LI – pre LI) --- Mean score ± SD and its clinical interpretation (pre LI vs. 2 to 3 weeks post LI)								
1	Yes	No	---	Noci: 44% Neuro: 44% Comb: 11% 55% had allodynia	-6.78mm	-1.11mm	0.03 ± 0.03 --- 0.52 ± 0.24 vs. 0.55 ± 0.22	0.12 ± 0.04 --- 0.64 ± 0.26 vs. 0.76 ± 0.22	-0.47 ± 0.28 --- 1.91 ± 0.68 *not much* vs. 1.44 ± 0.86 *not much* °	0.13 ± 0.20 --- 3.33 ± 0.73 *somewhat* vs. 3.46 ± 1.01 *somewhat*	-0.47 ± 0.24 --- 2.64 ± 0.88 *ambivalent* vs. 2.17 ± 0.87 *ambivalent* ° ~	0.30 ± 0.17 --- 2.53 ± 1.15 *ambivalent* vs. 2.83 ± 1.22 *ambivalent*	1.16 ± 0.26 **Δ --- 2.15 ± 1.18 *ambivalent* vs. 3.31 ± 0.80 *somewhat* °	0.40 ± 0.15 *Δ --- 0.87 ± 0.57 *not much* vs. 1.27 ± 0.81 *not much* °	-0.36 ± 0.27 --- 2.51 ± 0.76 *ambivalent* vs. 2.15 ± 0.83 *ambivalent*
2	No	No	-Less radio-frequency, TENS or neuro-stimulator. -Cause of pain: accident.	Noci: 44% Neuro: 19% Comb: 25% Only 6% had allodynia 8 LI in 13 months	-8.29mm	-12.44mm	0.08 ± 0.04 --- 0.49 ± 0.19 vs. 0.57 ± 0.20	0.17 ± 0.05 --- 0.60 ± 0.23 vs. 0.77 ± 0.22 °	-0.31 ± 0.46 --- 2.25 ± 0.61 *ambivalent* vs. 1.94 ± 0.88 *not much* °	0.72 ± 0.37 --- 3.03 ± 0.83 *somewhat* vs. 3.75 ± 1.02 *somewhat* °	-0.30 ± 0.30 --- 1.88 ± 1.13 *not much* vs. 1.58 ± 0.68 *not much*	0.68 ± 0.29 --- 2.48 ± 1.17 *ambivalent* vs. 3.16 ± 1.26 *somewhat* °	-0.87 ± 0.34 **Δ --- 2.33 ± 1.03 *ambivalent* vs. 1.46 ± 0.81 *not much* °	1.76 ± 0.26 **Δ --- 1.26 ± 1.24 *not much* vs. 3.02 ± 1.15 *somewhat* °	0.59 ± 0.39 * --- 1.93 ± 0.97 *not much* vs. 2.52 ± 0.88 *somewhat* °
3	No	Yes	-Higher pain intensity pre LI. -All reported pain in the head region. -Highest rate of narcotic users.	Noci: 38% Neuro: 50% Comb: 0% 50% had allodynia 6 LI in 19 months	-53.5mm ◊	-39.81mm ◊	0.03 ± 0.05 --- 0.52 ± 0.23 vs. 0.55 ± 0.31.	0.17 ± 0.05 --- 0.70 ± 0.25 vs. 0.87 ± 0.31 °	-0.63 ± 0.48 --- 1.93 ± 0.95 *not much* vs. 1.30 ± 1.00 *not much* °	0.36 ± 0.32 --- 3.47 ± 0.71 *somewhat* vs. 3.83 ± 1.10 *somewhat* °	0.68 ± 0.37 ** --- 1.50 ± 1.00 *not much* vs. 2.18 ± 1.22 *ambivalent* °	0.53 ± 0.30 --- 2.06 ± 1.36 *ambivalent* vs. 2.59 ± 1.23 *ambivalent*	0.44 ± 0.37 ** --- 3.29 ± 0.33 *somewhat* vs. 3.73 ± 1.03 *somewhat* ° ~	0.80 ± 0.30 *Δ --- 1.40 ± 0.83 *not much* vs. 2.20 ± 0.75 *ambivalent* °	-0.48 ± 0.45 --- 2.15 ± 0.59 *ambivalent* vs. 1.67 ± 1.02 *not much* °

** Significant difference in change scores between the groups; p < 0.05*
*** Significant difference in change scores between the groups; p<0.001*
Δ Significant difference from baseline score; p≤0.001

◊criterion-based change from baseline (≥28mm or ≥33%)
~borderline difference at baseline
°meaningful change from baseline (≥1/2SD)

Noci: nociceptive pain
Neuro: neuropathic pain
Comb: combined pain

7. DISCUSSION

This exploratory prospective study looked at many facets of the interactions between pain intensity, function and beliefs and attitudes towards pain for individuals who are receiving a LI. Sociodemographic characteristics suggested the following general picture of LI users: highly educated married women of approximately fifty years of age who have had pain for approximately ten years, who are not working because of their pain problem and are receiving a disability income. Therefore, the issues of gender, marital status and education do not impact on our findings. Regardless of which criterion was used to distinguish between those subjects who had pain reduction from those who did not on the fourth day post-infusion, every subject met or did not meet both criteria (either 28 mm or 33% decrease on a 100 mm VAS). Thus, we are confident that our three groups are representative of the classification criteria used for the group definitions. As there were repeat LI users who fell into groups that did and did not experience pain relief at four days post-infusion, the lack of pain relief for first time users might not be solely attributed to unrealistic expectations on what the LI would do for pain relief. Except for close to significance differences in pain factors and current treatments, the possible confounding variables related to socio-demographic characteristics were eliminated for group analysis. Thus, the group classification has provided an opportunity for descriptive baseline profiles of the three groups of LI users and explores how these profiles might predict the associations between pain intensity, beliefs and attitudes towards pain, and function following a LI.

7.1 Differences between the groups

7.1.1 First LI

7.1.1.1 Group 1- first time LI users, no pain decrease

This group showed the smallest decrease in pain intensity four days after their first LI trial. Paradoxically, they had the highest increase in the belief that 'medications are an appropriate treatment for chronic pain' going from *ambivalence* before the infusion (Table 4) to believing *somewhat* that 'medications are an appropriate treatment for chronic pain' two to three weeks after the infusion (Table 6).

Therefore, even though group 1 subjects did not report a significant pain intensity decrease, they believed more in the appropriateness of medications after they had their first LI. We can speculate that they might not associate LI with medication due to the concomitant increase in both pain intensity and belief that 'medications are an appropriate treatment for chronic pain', and the decrease in the belief 'in a Medical Cure for their pain problem' at either two or three weeks post-infusion. Since this treatment is more invasive than taking a pill, LI may, in this group, be seen as a medical treatment rather than medication. Therefore their scores on the SOPA-32 may reflect less faith in a Medical Cure because the pain was not decreased, and a concomitant hope that some type of medication would eventually help them to decrease their pain. This is a point of interest that could be explored more fully in a subsequent study that asked this question directly.

Another characteristic of this group is that they more strongly believed that 'they should avoid exercise' at baseline (Table 4) even if this difference between the groups did not reach significance ($p = 0.08$). Interestingly, their thoughts on this decreased after they received their first LI (Table 6). In the literature, a decrease in the harm subscale of the SOPA is associated with better function (Nielson & Jensen, 2004), and more active coping strategies (Lachapelle et al., 2005). However, the SMFA measurement indicated that function did not improve. Nevertheless, for these new lidocaine users, a little relief might give them hope that they could become more active in contrast to those in group 3 where the chronicity of the pain and the variation in pain relief over the periods between infusions seemed to have the opposite effect. This may be because of experience with pain when exercising for the latter group, and would support the idea that not being taught how to exercise while controlling pain leads to negative experiences that diminishes motivation to try becoming more active with pain (Motl, Konopack, Hu, & McAuley, 2006).

7.1.2 Groups with Previous LI

7.1.2.1 Group 2- repeat LI users, no pain decrease

At baseline, this group had four characteristics that were different from the other two groups, although they did not reach significance in this small sample: these subjects

were receiving less electro-modalities, their pain had predominantly been caused by an accident, fewer subjects had allodynia, and a smaller proportion of this group had neuropathic pain. The latter two characteristics could partly explain a poorer pain relief after a LI, according to Tremont-Lukats et al. (2003), who reported that LI can be effective for neuropathic pain and Attal et al. (2004) who found that response to LI was associated with the severity of mechanical allodynia in patients with peripheral neuropathic pain. It is also known that pain experience is partly influenced by contextual factors (Price, Hirsh, & Robinson, 2008); accident-related pain might not have the same meaning as pain due to an illness. In the same way, one might speculate that the cause of pain indirectly impacts on the changes in pain intensity, function and beliefs and attitudes towards pain following a LI. However, no study has looked at this aspect yet. As well, nothing appears in the literature about the impact of electro-modalities on the efficacy of a LI.

This group was *ambivalent* (Table 4) at baseline about the appropriateness of medications for chronic pain. However, two to three weeks post-infusion, they were the only group to show a significant decrease in this belief; they did *not believe much* that 'medications are an appropriate treatment for chronic pain' (Table 6). Moreover, group 2 subjects were the only ones to show a tendency to increase their belief 'in a Medical Cure for their pain problem'. They were *ambivalent* (Table 4) at baseline and *somewhat* believed 'in a Medical Cure for their pain problem' after the infusion (Table 6). Thus, a weaker belief in medications and a stronger belief in Medical Cure were concomitant with a slight but not meaningful pain intensity decrease after a LI for group 2 subjects. Perhaps the notion should be explored that some individuals might consider lidocaine to be a medication, even after information sessions have been held. Nevertheless, these individuals persevere with the LI treatment, and while they have not been using the intervention as long as group 3 (13 vs. 19 months), they tend to be more frequent in their use of LI (8 vs. 6 infusions). It would be interesting to investigate if receiving repeated LI is part of a cognitive pattern for this category of LI users that offers them the conviction that they are being taken care of. On the other hand, since no measures of pain intensity were taken later than 3 weeks post-infusion it might be possible that this slight pain relief persists after this period. A small but prolonged pain decrease may partly

justify why the LIs are continued. In that sense, further studies could explore if repeated LIs have a gradual and longer action for this category of users since it is known that the duration of the analgesic effect of LI may vary depending on the pain condition, for example (Attal et al., 2000).

In addition, these subjects exceptionally tended to believe more that 'their emotions impact their experience of pain' after the infusion. Keeping in mind that Jensen et al. (2000) found that an increased score on the Emotion subscale was associated with depression, it would have been interesting to know if group 2 subjects showed more depression symptoms than the others. This aspect could not be considered in this exploratory study due to the lack of appropriate information in the charts, but should be measured in future studies.

7.1.2.2 Group 3- repeat LI users, pain decrease

These are the subjects who had the greatest benefit from the LI, as there seems to be a clear tendency for pain intensity to rapidly decrease after the infusion and then to gradually rebound, but still at a much lower than pre-infusion level. They are mainly distinguished from the other groups by their pain and medication profiles.

In fact, these subjects had much higher baseline pain intensity. This distinction is congruent with the findings of Carroll et al. (2007) that higher pain intensity increases the odds of being a lidocaine responder. In that study, subjects were not receiving a first LI and the mean pain intensity of those who benefited from the infusion was 67 (vs. 80.75 for group 3 in the present study) and 59 (vs. 59.11 for group 1 and 58.0 for group 2 in the present study) for the non responders.

On top of being more intense, pain was present for a longer period of time and was also more diffuse for group 3 subjects since they all had pain in more than three sites of their body (compared to 56% in group 1 and 69% in group 2) and included the head region for all of them. Although these items did not reach statistical significance in this small sample, it should be considered in subsequent studies regarding pain relief following a LI, as it could be that the more numerous the sites the easier it is to perceive a reduction in pain.

Correspondingly with the important pain decrease after the infusion, group 3 subjects had the highest belief that 'medications are an appropriate treatment for chronic pain' with a small standard deviation at baseline. These subjects *somewhat* believed that 'medications are an appropriate treatment for chronic pain' before receiving the infusion (Table 4) whereas the other groups were *ambivalent* (Table 6). Interestingly, this belief tended to increase while their belief 'in a Medical Cure for their pain problem' showed the opposite trend after the infusion (Table 6). These results reveal that they most probably associate LI with medication which they receive on a regular basis and that they are convinced it is helpful for them. It could be that their previous positive experiences with LI increased their belief in medication. This is congruent with the idea that prospective expectations may partly explain important reported pain intensity variations (Price et al., 2008; Price, Chung, & Robinson, 2005; Vase, Robinson, Verne, & Price, 2003).

It should also not be ignored that this group included the highest proportion of users of opioids even though it did not reach significance. Although Carroll et al. (2007) found no correlation between previous trials of opioid medication and analgesic response to LI, this observation is congruent with the study by Jensen et al. (2000) that found that a higher belief in medication was associated with the use of more opioid medications. Investigating more precisely if there is a link between using narcotics, believing in the appropriateness of medications and pain intensity variation pattern following a LI is of interest for further studies.

7.2 Commonalities between the groups

7.2.1 Beliefs and attitudes towards pain (SOPA-32) profile

In general, subjects of the three groups were similar at baseline regarding five of the seven subscales of the SOPA-32; they were close to ambivalence regarding their belief that 'they can control their pain', that 'their emotions impact their experience of pain' and 'their belief in a Medical Cure for their pain problem'; they felt that 'they are disabled by their pain' and they *disagreed a little* that 'others, especially family members, should be solicitous in response to their experience of pain'. After the LI, all three groups

showed a meaningfully weaker belief that 'they can control their pain', and a significantly stronger belief that 'others, especially family members, should be solicitous in response to their experience of pain'. In addition, repeat LI users (groups 2 and 3) felt they were more 'disabled by their pain' after the LI. Those observations are in accordance with the SOPA profile Jensen et al. 2000 described as being associated with a *more illness focus or passive style of pain management.* This aspect will be developed in point 7.2.3.

The fact that every group included in this study were hoping for more solicitude from their peers after they received a LI also is of special interest. Indeed, it is known social support interferes in the associations between pain intensity and function (Lopez et al., 2008; Osborne et al., 2007; Gil et al., 1987). In this study, the increase in the belief that 'others, especially family members, should be solicitous in response to their experience of pain' was particularly manifest for repeat LI users who did not report criterion-based pain intensity decrease after the LI (group 2). One may speculate that receiving a repetitive treatment which does not offer satisfying relief promotes this belief. For subjects who reported pain relief after a LI (group 3), this pattern might be due to their desire to prolong their relief by relying more on help from their peers in their every-day activities. However, for group 1, the pre and post-infusion scores correspond to the same clinical interpretation: they don't believe much that 'others, especially family members, should be solicitous in response to their experience of pain'.

In clinical practice, it is always essential to consider that the nature (positive/negative, passive/active, adaptive/maladaptive) of specific beliefs and attitudes towards pain is contextual. Depending on the type of treatment offered and the objectives targeted by a specific intervention, the same scores can be interpreted differently. In a study on cancer patients (Lai et al., 2002), those with higher medication beliefs and lower control beliefs were more likely to be adherent to prescribed pain medicine. The authors discussed that the necessity of analgesics was obvious in this population because of the perceived benefit it provided them. Concomitantly, although control beliefs were negatively associated with analgesic adherence, a higher sense of control over pain was favored in this context where 'the challenge to health care professionals is how to simultaneously enhance patients' sense of control over pain and strengthen accurate

knowledge and concepts about taking analgesic as prescribed' (p. 421). That being said, the validity of believing in the appropriateness of medications might depend on which medications are used, their dosage and their benefits and side effects perceived by the patient.

In the present study, the interactions between pain decrease and the belief in appropriateness of medications were different in each group. Repeat LI users (groups 2 and 3) might have associated LI with a kind of medication and those who reported criterion-based pain intensity decrease (group 3) more strongly believed that 'medications are an appropriate treatment for chronic pain' at baseline. In this case, where this intervention is available and suitable, believing in helpfulness of medication was a positive attitude. However, it could be negative when it has to be stopped or maladaptive if the objectives of the current treatments aimed at improving pain management skills and function and if the individual does not use active pain coping strategy. This aspect will be discussed in point 7.2.3.

7.2.2 No changes in function (SMFA)

In this study, in concordance with the literature (Vlaeyen et al., 1995; Rainville et al., 1992; Moran & Strong, 1995; Alschuler et al., 2007), changes in function were not directly associated with pain intensity.

As measured with the SMAF, function was remarkably low for both indices compared to the norms and was not improved for any group after the LI. The majority of the subjects in the three groups were receiving disability income, thus the aspect of disability income could be a motivator for maintenance of disability (Chibnall & Tait, 1994; Arnstein et al., 1999). However, as it will be discussed in the next section of this thesis, the coping strategies adopted by those subjects and their knowledge on how to exercise and stay active despite their chronic pain are most likely to have a deeper influence on the absence of functional improvement.

7.2.3 Overall pain management strategy

Regardless of whether or not LI reduced pain intensity, it appears that it has promoted an increase in a *more illness focus or passive style of pain management* (Jensen et al., 2000) within each group included in this study. According to Jensen et al. (2000), individuals with such beliefs and attitudes profiles (point 7.3.1) employ more passive pain coping strategies such as more frequent physician visits for their pain problem, pain-contingent medication use, guarding, resting, and asking for assistance. This tendency to adopt this pain management style was particularly manifest for the groups that had previously experienced LI (groups 2 and 3). Group 1 did not show this tendency as clearly as the others since their belief that 'exercise should be avoided' was decreased after they received their first LI, which can be considered a change towards a *self-management orientation* (Jensen et al., 2000). Thus, it seems that experiencing multiple LI may orient regular lidocaine patients towards a more passive pain management style.

However, based on this study alone, we cannot say if these changes are progressive and in the direction of a more passive style of coping with increased time and LI number, as we only looked at a window of time for this process. It could be that these attitudes cycle in the interval between infusions, going to a more passive strategy of pain management within the three weeks post-infusion, and becoming less passive as the next infusion approaches. It might be interesting in the future to observe two to three consecutive cycles to clarify this issue.

Interestingly, the results discussed in sections 7.2.1 and 7.2.2 are in accordance with previous research that identified correlations between specific SOPA subscales and function. As mentioned in the literature review, lower function was associated with lower scores on the Control subscale, higher scores on the Disability scale, and higher scores on the Solicitude scale (Strong et al., 1990; Nielson & Jensen, 2004; Lachapelle et al., 2005; Jensen et al., 2000; Jensen et al., 1994).

Curiously, even the significant reported pain relief after the LI for group 3 subjects did not have a positive impact on function. Moreover, their beliefs that 'they are disabled by their pain' and that 'they should avoid exercise' tended to increase after the infusion

whereas the other groups showed an opposite tendency for the latter belief. In the present situation, it could be that these subjects have signs of kinesiophobia, and may want to avoid exercises in order to prolong the substantial pain decrease they have following the infusion. As a matter of fact, some authors debated the question of the associations between kinesiophobia, function and pain intensity. For example, a study by Thomas, France, Lavender, and Johnson (2008) on individuals recently recovered from a recent episode of low back pain, found that those with high pain-related fear and kinesiophobia showed slower lumbar and hip motion in reaching tasks even 4 weeks after resolution of back pain. Another recent study (George, Dover, & Fillingim, 2007) on healthy subjects who underwent a procedure that induces muscle soreness at the shoulder, found that "clinical pain intensity and fear of pain explained 50% of the variance in upper-extremity disability" (p. 76), while only 11% was explained by pain intensity alone. Also, in patients with posttraumatic neck pain disability, Nederhand, Hermens, Ijzerman, Groothuis, and Turk (2006) found that "an increased level of both fear of movement... and pain intensity... were independently associated with a decreased level of muscle activation. Moreover, the results suggest that the association between fear of movement and lower muscle activity level is stronger in patients reporting high pain intensity..." (p. 519). In fact, group 3 subjects were those who had the highest baseline pain intensity.

Another possible explanation for the fact that function did not increase while the SOPA-32 Harm subscale increased after the LI is that group 3 subjects might not have the knowledge or the self-efficacy for doing exercises without increasing their pain (Coughlin, Badura, Fleisher, & Guck, 2000). This argument is supported by a previously cited study by Woby et al. (2007) that found that low self-efficacy and elevated pain-related fear lead to greater disability. Also, higher self-efficacy was associated with lower pain intensity, disability, and psychological distress and greater use of task persistence and less use of rest to cope with pain in chronic temporomandibular disorder pain patients (Turner et al., 2005). Again, these hypotheses could be explored in further studies.

In light of those observations, we suggest that patients receiving repeated LI for pain relief concomitantly take part in a graded activity and exercise program that includes

pain management training. After many years living with pain and not being able to do their daily activities the same way as before, these individuals need to learn how to exercise and accomplish their daily activities without increasing their pain. Active practice sessions with rehabilitation specialists (occupational therapist, exercise physiologist, physical educator, and physical therapist) could orient these regular lidocaine patients towards a *self-management orientation* (Jensen et al., 2000) and a better level of function. For example, Rainville et al. (1992) found a significant improvement in physical performance with no significant pain decrease in patients with chronic low back pain following a functional restoration rehabilitation program; they suggested that "it is possible that these successful physical experiences unlink patients' past behaviours and beliefs for which physical performance and pain were connected" (p. 1063). Indeed, literature reports that such interventions lead to gradual decrease pain-related fear, and improvements in activity tolerance, self-efficacy (Stanos & Houle, 2006), perceptions of personal control over pain (Coughlin et al., 2000), and functional capacity (Redondo et al., 2004). It also favors adoption of new or better skills and coping strategies, and more adequate acceptance of an altered life situation (Persson, Rivano-Fischer, & Eklund, 2004).

In our study population, the challenge would then be to promote belief that 'they can control their pain', and decrease beliefs that 'they are disabled by their pain' and 'that exercise should be avoided', while fostering belief in the appropriateness of medications through active practice. These patients would continue benefiting from regular LI while adopting a more active pain management style and improve their ability to perform their daily activities.

7.3 Associations of independent variables on the efficacy of LI

Even though Carroll et al. (2007) found that 'each decade of advancing age increases the odds of being a lidocaine responder by 36%', age was not a factor for the differences observed across the groups, as age was not significantly different between groups. However, subjects who had higher baseline pain intensity effectively reported the most important relief four days after the LI. Moreover, statistical analyses revealed that

subjects who believed more 'that medications are an appropriate treatment for chronic pain' and less 'that they should avoid exercise', had higher chances of experiencing a decrease in pain intensity four days after a LI. This is a novel finding since the beliefs and attitudes towards pain of individuals undergoing LI has never been explored before.

Because Attal et al. (2004) found an association between the severity of mechanical allodynia and the analgesic effect of intravenous lidocaine, we looked to see if there was a similar association between the LI effect and presence of allodynia. Indeed, half the subjects in the group 3, who had better relief after the infusion, had neuropathic pain and allodynia. However, group 1 had similar pain characteristics and did not benefit from the infusion. This disparity may indicate that persons with mechanical allodynia need to have repeated LI to report a detectibly significant decrease in pain intensity. On the other hand, group 2' pain categories were more disparate and only one subject had allodynia. Pain intensity tended to slightly decrease in time for those subjects. Thus from our data, it could be conjectured that this association is not a tightly coupled one, and that there could be other factors that affect the efficacy of LI. This aspect could be added to further studies as this question deserves further investigation.

8. CONCLUSION

This study is a starting point for exploring prospectively the interactions between pain intensity, function and beliefs and attitudes towards pain after a LI. Its limits might be overcome by further studies. First, the sample was small and heterogeneous regarding pain localization. It may have diminished the possibility to detect functional changes using the SMFA. We believe than further research needs to be done with a larger (approximately seventy subjects in each group) and more homogenous sample regarding pain localization. We chose to use the SMFA because it is a tool comprising generalized questions designed to detect change in a heterogeneous sample of pain localization. Also, we hoped that the Bother Index could give additional and interesting information. Using a measurement tool that would address functional tasks that imply specific regions of the body would be more responsive and better detect changes which is in accordance with a recent article assessing the utilization, interpretation, and reporting of SMFA (Barei et al., 2007). Further studies could use, for example, the Pain Disability Index, which is more commonly used, until there is an interpretation grid for both SMFA indicies' scores and the minimal meaningful change is set.

While it is not possible to solidly conclude that LI do not impact on function, this exploratory study revealed some associations between the group variable and specific beliefs and attitudes towards pain as measured by the Medication, Harm, Solicitude and Medical Cure SOPA-32 subscales. In addition, it has been shown that this intervention can have a significant impact on the Medication and Solicitude subscales. Along with those results, meaningful associations between the group variables and each SOPA-32 subscale were found but did not reach statistical significance in our small sample since. They also are of great interest for future studies.

Studies on larger samples should also include additional confounding variables; depression (Alschuler et al., 2007), anxiety (Ploghaus et al. 2001), catastrophizing (Sullivan et al., 2001; Sullivan et al., 2005), fear-avoidance beliefs and kinesiophobia (Waddell et al., 1993; Pells et al., 2007; Burwinkle et al., 2005; Swinkels-Meewisse et al., 2006), self-efficacy beliefs (Arnstein et al., 1999; Woby et al., 2007), and pain-coping

strategies (Nielson & Jensen, 2004; LaChapelle et al., 2005; Roth & Geisser, 2002; Jensen et al., 2000; Osborne et al., 2007) should ideally be considered since they are known to affect pain perception and disability.

Little has been done to identify the patients most likely to benefit from LI and the few studies that exist were done on a small number of patients, lack placebo groups and barely considered other factors that could be associated with analgesia according to a recent study (Carroll, 2007). In light of our findings, we strongly believe that pre selection of patients who would benefit from LI may be enhanced using the SOPA-32. Moreover, since pain decrease is not the ultimate goal of treatment, beliefs and attitudes towards pain should directly be addressed to help patients fully benefit from this intervention and help them improve their ability to perform their daily activities.

To conclude, this exploratory study opens many doors for future investigations such as:

- Does a graded activity and exercise program improve function in patients whose pain is decreased by a LI in comparison to those who don't?

- Do LI users with mechanical allodynia report greater decrease in pain after they received repeated infusions then after a first infusion?

- Do electro-modalities impact on the efficacy of LI?

- Is there a link between using narcotics, believing in the appropriateness of medications for chronic pain and/or pain relief after a LI?

- Do LI users consider this intervention as being a type of medication or a medical treatment; and is this conception influenced by specific factors such as being a responder or not, and having received previous LI or not?

and,

which specific attitudes and beliefs toward pain:

1. impact on pain decrease after a LI in persons with more diffuse pain in comparison to those with localized pain?

2. explain the finding that repeat LI users who report pain intensity decrease after the infusion, show stronger belief that 'they should avoid exercise' after the infusion?

3. are involved in the tendency for repeat LI users to adopt a more passive pain management style then first LI users?

4. are involved in repeat LI users who continue seeking repeated LI even if they don't report detectibly significant pain intensity decrease after the infusion?

REFERENCES

Aaronson N.K., Acquadro C., Alonso J., Apolone G., Bucquet D., Bullinger M., et al. (1992). International Quality of Life Assessment (IQOLA) Project. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation,* 1(5): 349-351.

Abresch R.T., Carter G.T., Jensen M.P., Kilmer D.D. (2002). Assessment of pain and health-related quality of life in slowly progressive neuromuscular disease. *American Journal of Hospice & Palliative Care,* 19(1): 39-48.

Alschuler K.N., Theisen-Goodvich M.E., Haig A.J., Geisser M.E. (2008). A comparison of the relationship between depression, perceived disability, and physical performance in persons with chronic pain. *European Journal of Pain,* 12(6): 757-764.

Apkarian V.A., Bushnell C.M., Treede R.D., Zubieta J.K. (2005). Human brain mechanisms of pain perception and regulation in health and disease. *European Journal of Pain,* 9 : 463–484.

Arnsetin P. (2000). The mediation of disability by self efficacy in different samples of chronic pain patients. *Disability and rehabilitation,* 22(17): 794-801.

Arnstein P., Caudill M., Mandle C.L., Norris A., Beasley R. (1999). Self efficacy as a mediator of the relationship between pain intensity, disability and depression in chronic pain patients. *Pain,* 80: 483-491.

Asenlöf P., Denison E., Lindberg P. (2005). Individually tailored treatment targeting activity, motor behavior, and cognition reduces pain-related disability: a randomized controlled trial in patients with musculoskeletal pain. *The Journal of Pain,* 6(9): 588-603.

Attal N., Gaudé V., Brasseur L., Dupuy M., Guirimand F., Parker F., et al. (2000). Intravenous lidocaine in central pain, a double-blind, placebo controlled, psychophysical study. *Neurology,* 54: 564-574.

Attal N., Rouaud J., Brasseur L. (2004). Systemic lidocaine in pain due to peripheral nerve injury and predictors of response. *Neurology,* 62: 218-225.

Backonja M., & Gombar K. (1992). Response of central pain syndromes of intravenous lidocaine. *Journal of Pain and Symptom Management,* 7: 172-178.

Backonja M.M., & Galer B.S. (1998). Pain assessment and evaluation of patients who have neuropathic pain. *Neurologic Clinics,* 16: 775-790.

Baliki M.N., Geha P.Y., Apkarian A.V., Chialvo D.R. (2008). Beyond feeling: chronic pain hurts the brain, disrupting the default-mode network dynamics. *Journal of Neuroscience,* 28: 1398-1403.

Ballantyne J. (2002). *The Massachusetts General Hospital Handbook of Pain Management.* 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins.

Bantick S.J., Wise R.G., Ploghuaus A., Clare S., Smith S.M., Tracey I. (2002). Imaging how attention modulates pain in humans using functional MRI. *Brain,* 125: 310-319.

Barei D.P., Agel J., Swiontkowski M.F. (2007). Current Utilization, Interpretation, and Recommendations: The Musculoskeletal Function Assessments (MFA/SMFA). *Journal of Orthopaedic Trauma,* 21(10): 738-742.

Baron R., & Tolle T. (2008). Assessment and diagnosis of neuropathic pain. *Current Opinion in Supportive & Palliative Care,* 2(1): 1-8.

Bartlett E.E., & Hutaserani O. (1961). Xylocaine for the relief of postoperative pain. *Anesthesia and Analgesia,* 40: 296-304.

Bergner M., Bobbitt R.A., Carter W.B., Gilson B.S. (1981). The SIP: development and final revision of a health status measure. *Health Care,* 19: 787-805.

Bolwijn P.H., van Santen-Hoeufft M.H.S., Baars H.M.J., van der Linden S. (1994). Social Network Characteristics in Fibromyalgia or Rheumatoid Arthritis. *Arthritis Care and Research,* 7(1): 46-50.

Boulanger A., Clark A.J., Squire P., Cui E., Horbay G.L. (2007). Chronic pain in Canada: have we improved our management of chronic noncancer pain? *Pain Research & Management,* 12(1): 39-47.

Brooks J., & Tracey I. (2005). From nociception to pain perception: imaging the spinal and supraspinal pathways. *Journal of Anatomy,* 207: 19-33.

Buitenhuis J., Jaspers J.P., Fidler V. (2006). Can kinesiophobia predict the duration of neck symptoms in acute wiplash? *The Clinical Journal of Pain,* 22(3): 272-277.

Burwinkle T., Robinson J.P., Turk D.C. (2005). Fear of movement: factor structure of the tampa scale of kinesiophobia in patients with fibromyalgia syndrome. *The Journal of Pain,* 6(6): 384-391.

Carroll I., Gaeta R., Mackey S. (2007). Multivariate analysis of chronic pain patients undergoing lidocaine infusions: increasing pain severity and advancing age predict likelihood of clinically meaningful analgesia. *The Clinical Journal of Pain,* 23(8): 702-706.

Chibnall J.T., & Tait R.C. (1994). The Pain Disability Index: factor structure and normative data. *Archives of Physical Medicine and Rehabilitation,* 75: 1082-1086.

Coderre T.J., Katz J., Vaccarino A.L., Melzack R. (1993). Contribution of central neuroplasticity to pathological pain: review of clinical and experimental evidence. *Pain,* 52: 259-285.

Coughlin B.A., Badura A.S., Fleischer T.D., Guck T.P. (2000). Multidisciplinary Treatment of Chronic Pain Patients: Its Efficacy in Changing Patient Locus of Control. *Archives of Physical Medicine and Rehabilitation,* 81: 739-740.

De Clive-Lowe S.G., Desmond J., North J. (1958). Intravenous lidocaine anesthesia. *Anesthesiology,* 13: 138-146.

Denison E., Asenlöf P., Sandborgh M., Lindberg P. (2007). Musculoskeletal pain in primary health care: subgroups based on pain intensity, disability, self-efficacy, and fear-avoidance variables. *The Journal of Pain,* 8(1): 67-74.

Disability in Canada: A 2001 Profile. (2008). Office for Disability Issues. Human Resources Development Canada (December 2003). Retrieved February 27th, 2006 from http://dsp-psd.pwgsc.gc.ca/Collection/RH37-4-4-2001E.pdf. Last updated September 16th.

Duquette J., McKinley P.A., Jacques A. Oléa E., Tapin N. (2006). Comparaison de deux versions abrégées du Questionnaire sur les attitudes envers la douleur. 7e Congrès québécois en réadaptation, Montréal (Canada).

Duquette J., McKinley P.A., Litowski J. (2005). Test-retest reliability and internal consistency of the Quebec-French version of the survey of pain attitudes (QAD/F-SOPA). *Archives of Physical Medicine and Rehabilitation,* 86(4): 782-788.

Duquette J., McKinley P.A., Litowski J. (2001). Traduction et pré-test du Questionnaire sur les attitudes envers la douleur (Survey of Pain Attitudes). *Revue Québécoise d'Ergothérapie,* 10: 23-30.

Evans S., Weinberg B.A., Spielman L., Fishman B. (2003). Assessing negative thoughts in response to pain among people with HIV. *Pain,* 105 (1-2): 239-245.

Farrar J.T., Young Jr. J.P., LaMoreaux L., Werth J.L., Poole R.M. (2001). Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain,* 94 (2): 149-158.

Finch E., Brooks D., Stratford P.W., Mayo N.E. (2002). *Physical Rehabilitation Outcome Measures A Guide to Enhanced Clinical Decision Making.* 2nd ed. Edited by Finch E, Brooks D, Stratford PW, Mayo NE. Hamilton, Ontario: BC Decker Inc.

Galer B.S., Miller KV., Rowbotham M.C. (1993). Responses to intravenous lidocaine infusion differs based on clinical diagnosis and site of nervous system injury. *Annals in Neurology,* 43: 1233-1235.

Gauthier N., Thibault P., Sullivan M.J. (2008). Individual and Relational Correlates of Pain-related Empathic Accuracy in Spouses of Chronic Pain Patients. *Clinical Journal of Pain,* 24 (8): 669-677.

George S.Z., Dover G., Fillingim R.B. (2007). Fear of pain influences outcomes after exercise-induced delayed onset muscle soreness at the shoulder. *The Clinical Journal of Pain,* 23(1): 76-84.

Gerstle D.S., All A.C., Wallace D.C. (2001). Quality of life and chronic nonmalignant pain. *Pain Management Nursing,* 2(3): 98-109.

Giardino N.D., Jensen M.P., Turner J.A., Ehde D.M., Cardenas D.D. (2003). Social environment moderates the association between catastrophizing and pain among persons with a spinal cord injury. *Pain,* 106: 19-25.

Gil K.M., Keefe F.J., Crisson J.E., Van Dalfsen P.J. (1987). Social support and pain behaviour. *Pain,* 29: 209-217.

Gilbert R.A., Hanson I.R., Brown A.B. (1951). Intravenous use of xylocaine. *Anesthesia and Analgesia,* 30: 301-313.

Guyatt G.H., Osoba D., Wu A.W., Wyrwich K.W., Norman G.R., and the Clinical Significance Consensus Meeting Group. (2002) Methods to explain the clinical significance of health status measures. *Mayo Clinic Proceedings,* 77: 371-383.

Haythornthwaite J.A., & Benrud-Larson L.M. (2000). Psychological aspects of neuropathic pain. *The Clinical Journal of Pain,* (16): S101-105.

In collaboration. (2006). *SPSS 15.0 Command Syntax Reference.* Chicago, Illinois: SPSS inc.

International Classification of Functioning, Disability and Health. WHO. Retrieved February 27th, 2006 from http://www3.who.int/icf/. Last updated September 16th, 2008.

Jensen M.P., Chen C., Brugger A.M. (2003). Interpretation of visual analog scale ratings and change scores: a reanalysis of two clinical trials of postoperative pain. *The Journal of Pain,* 4(7): 207-214.

Jensen M.P., & Karoly P. (1992). Pain-specific beliefs, perceived symptom severity, and adjustment to chronic pain. *The Clinical Journal of Pain,* 8: 123-130.

Jensen M.P., Karoly P., Chant D. (1987). The development and preliminary validation of an instrument to assess patient's attitude towards pain. *Journal of Psychometric Research,* 31: 393-400.

Jensen M.P., Nielson W.R., Turner J.A., Romano J.M., Hill ML. (2004). Changes in readiness to self-manage pain are associated with improvement in multidisciplinary pain treatment and pain coping. *Pain,* 111: 84-95.

Jensen M.P., Romano J.M., Turner J.A., Good A.B., Wall L.H. (1999). Patient's beliefs predict patient functioning: further support for a cognitive-behavioral model of chronic pain. *Pain,* 81: 95-104.

Jensen M.P., Turner J.A., Romano J.M. (2000). Pain belief assessment: A comparison of the short and long versions of the Survey of Pain Attitudes. *The Journal of Pain,* 1(2): 138-150.

Jensen M.P., Turner J.A., Romano J.M., Lawler B. (1994). Relationship of pain-specific beliefs to chronic pain adjustment. *Pain,* 57(3): 301-309.

Jovey R.D. (2002). Chronic non-cancer pain. In: Jovey R.D (Ed.), *Managing Pain, The Canadian Healthcare Professional's Reference.* (pp.113-128). Toronto: Healthcare and Financial Publishing.

Jovey R.D. Wait time alliance needs to consider pain. Canadian Pain Society Press Release. Retrieved September 1st, 2008 from www.canadianpainsociety.ca/pressreleasecpsnov82005. Last updated September 16th, 2008.

Keefe F.J., Lefebvre J.C., Egert J.R., Affleck G., Sullivan M.J., Caldwell D.S. (2000). The relationship of gender to pain, pain behavior, and disability in osteoarthritis patients: the role of catastrophizing. *Pain,* 87(3): 325-334

Keogh E., McCracken L.M., Eccleston C. (2005). Do men and women differ in their response to interdisciplinary chronic pain management? *Pain,* 114: 37-46.

Keogh E., McCracken L.M., Eccleston C. (2006). Gender moderates the association between depression and disability in chronic pain patients. *European Journal of Pain,* 10(5): 413-422.

Klooster P.M., Drossaers-Bakker K.W., Taal E., van de Laar M.A.F.J. (2006). Patient-perceived satisfactory improvement (PPSI): Interpreting meaningful change in pain from the patient's perspective. *Pain,* 121 (1-2): 151-157.

LaChapelle D., Hadjistavropoulos T., Dever T. (2005). Relationships among pain appraisals, coping, and adjustment to chronic arthritis and fibromyalgia pain. *Pain Research & Management,* 10: 102-105.

Lai Y.H., Keefe F.J., Sun W.Z., Tsai L.Y., Cheng P.L., Chiou J.F, et al. (2002). Relationship Between Pain-Specific Beliefs and Adherence to Analgesic Regimens in Taiwanese Cancer Patients: A Preliminary Study. *Journal of Pain and Symptom Management,* 24(4): 415-423.

Lamé I.E., Peters M.L., Vlaeyen J.W.S., Kleef M.V., Patijn J. (2005). Quality of life in chronic pain is more associated with beliefs about pain, than with pain intensity. *European Journal of Pain,* 9: 15-24.

López-Martínez A.E., Esteve-Zarazaga R., Ramírez-Maestre C. (2008). Perceived Social Support and Coping Responses Are Independent Variables Explaining Pain Adjustment Among Chronic Pain Patients. *The Journal of Pain,* 9(4): 373-379.

Lynch M.E., Clark A.J., Sawynok J., Sullivan M.J. (2005). Topical Amitriptyline and Ketamine in Neuropathic Pain Syndromes: An Open-Label Study. *Anesthesiology,* 103: 140-146.

MacLaren J.E., Gross R.T., Sperry J.A., Boggess J.T. (2006). Impact of Opioid Use on Outcomes of Functional Restoration. *The Clinical Journal of Pain,* 22(4): 392-398.

Mao J., & Chen L.L. (2000). Systemic lidocaine for neuropathic pain relief. *Pain,* 87: 7-17.

Markman J.D., & Oaklander A.L. (2002). In Ballantyne J. (Ed.), *The Massachusetts General Hospital Handbook of Pain Management* 2nd ed. (pp. 339-359). Philadelphia: Lippincott Williams & Wilkins.

Meier T., Wasner G., Faust M., Kuntzer T., Ochsner F., Hueppe M., et al. (2003). Efficacy of lidocaine patch 5% in the treatment of focal peripheral neuropathic pain syndromes: a randomized, double-blind, placebo-controlled study. *Pain,* 106(1-2): 151-158.

Melzack R. (1999). From the gate to the neuromatrix. *Pain Supplement,* 6: S121-126.

Melzack R. (2005). Evolution of the Neuromatrix Theory of Pain. The Prithvi Raj Lecture: Presented at the Third World Congress of World Institute of Pain, Barcelona 2004. *Pain Practice,* 5 (2): 85-94.

Melzack R., & Loeser J.D. (1978). Phantom body pain in paraplegics: evidence for a central 'pattern generating mechanism' for pain. *Pain,* 4: 195-210.

Melzack R., & Wall P.D. (1965). Pain mechanisms: a new theory. *Science,* 150: 971-979.

Merskey H., Lindblom U., Mumford J.M., Nathan P.W., Sunderland S. (1994). Pain Terms. In Merskey H & Bogduk N (Eds.), *Classification of chronic pain: descriptions of chronic pain syndromes and definitions of terms.* 2nd ed. (pp. 209-213). Seattle: IASP Press.

Miron D., Ducan G.H., Bushnell M.C. (1989). Effects of attention on the intensity and unpleasantness of thermal pain. *Pain,* 39: 345-352.

Motl R.W., Konopack J.F., Hu L., McAuley E. (2006). Does self-efficacy influence leg muscle pain during cycling exercise? *The Journal of Pain,* 7(5): 301-307.

Moran M., & Strong J. (1995). Outcomes of a rehabilitation programme for patients with chronic back pain. *The British Journal of Occupational Therapy,* 58(10): 435-438.

Moulin D.E., Clark A.J., Speechley M., Morley-Forster P.K. (2002). Chronic Pain in Canada – Prevalence, treatment, impact and the role of opioid analgesia. *Pain Research & Management,* 7(4): 179-184.

Murray T.J. Chronic pain. Workers Compensation Board of Nova Scotia. Retrieved February 1st, 2006 from www.wcb.ns.ca/chronicpain.pdf. Last updated February 27th, 2006.

Nederhand M.J., Hermens H.J., Ijzerman M.J., Groothuis K.G., Turk DC. (2006). The effect of fear of movement on muscle activation in posttraumatic neck pain disability. *The Clinical Journal of Pain,* 22(6): 519-525.

Nielsen W.R., & Jensen M.P. (2004). Relationship between changes in coping and treatment outcome in patients with fibromyalgia syndrome. *Pain,* 109(3): 233-241.

Osborne T.L., Jensen M.P., Ehde D.M., Hanley M.A., Kraft G. (2007). Psychosocial factors associated with pain intensity, pain-related interference, and psychological functioning in persons with multiple sclerosis and pain. *Pain,* 127(1-2): 52-62.

Pells J., Edwards C.L., McDougald C.S., Wood M., Barksdale C., Jonassaint J., et al. (2007). Fear of movement (kinesiophobia), pain, and psychopathology in patients with sickle cell disease. *The Clinical Journal of Pain,* 23(8): 707-713.

Persson E., Rivano-Fischer M., Eklund M. (2004). Evaluation of changes in occupational performance among patients in a pain management program. *The Journal of Rehabilitation Medicine,* 36: 85-91.

Pertovaara A., Wei H., Hamalainen M.M. (1996). Lidocaine in the rostroventromedial medulla and the periaqueductal gray attenuates allodynia in neuropathic rats. *Neuroscience Letters,* 218: 127-130.

Ploghaus A., Narain C., Beckmann C.F. (2001). Exacerbation of pain by anxiety is associated with activity in a hippocampal network. *The Journal of Neuroscience,* 21: 9896-9903.

Price D.D., Chung S.K., Robinson M.E. (2005). Conditioning, expectation, and desire for relief in placebo analgesia. *Seminars in Pain Medicine,* 3(1): 15-21.

Price D.D., Hirsh A., Robinson M.E. (2008). Psychological Modulation of Pain. *The Senses: A Comprehensive Reference,* 5: 975-1002.

Puhan M.A., Frey M., Büchi S., Schünemann H.J. (2008). The minimal important difference of the hospital anxiety and depression scale in patients with chronic obstructive pulmonary disease. *Health and Quality of Life Outcomes,* 6: 46.

Rainville J., Ahern D.K., Phalen L., Childs L.A., Sutherland R. (1992). The association of pain with physical activities in chronic low back pain. *Spine,* 17(9): 1060-1064.

Rainville P., Duncan G.H., Bushnell M.C. (2002). Représentation cérébrale de l'expérience subjective de la douleur chez l'homme. *Les sélections de médecine/sciences,* 23: 21-30.

Redondo J.R., Justo C.M., Moraleda F.V., Velayos Y.G., Puche J.J.O., Zubero J.R., et al. (2004). Long-term efficacy of therapy in patients with Fibromyalgia: a physical exercise-based program and a cognitive-behavioral approach. *Arthritis & Rheumatism (Arthritis Care & Research,* 51(2): 184-192.

Rome J.D., Townsend C.O., Bruce B.K., Sletten C.D., Luedtke C.A., Hodgson J.E. (2004). Chronic noncancer pain rehabilitation with opioid withdrawal: comparison of treatment outcomes based on opioid use status at admission. *Mayo Clinic Proceedings,* 79: 759-768.

Roth R.S., & Geisser M.E. (2002). Educational Achievement and chronic pain disability: mediating role of pain-related cognitions. *Pain,* 109(3): 233-241.

Rowbotham M.C. (2001). What is a 'clinically meaningful' reduction in pain? *Pain,* 94(2): 131-132.

Rucker K.S., & Metzler H.M. (1995). Predicting subsequent employment status of SSA disability applicants with chronic pain. *Clinical Journal of Pain,* 11: 22-35.

Salaffi F., Stancati A., Silvestri C.A., Ciapetti A., Grassi W. (2004). Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *European Journal of Pain,* 8(4): 283-291.

Sandborgh M., Lindberg P., Denison E. (2007). The Pain Belief Screening Instrument (PBSI): Predictive validity for disability status in persistent musculoskeletal pain. *Disability and Rehabilitation,* 1-8. [Epub ahead of print]

Schanberg L.E., Sandstrom M.J., Starr K., Gil K.M., Lefebvre J.C., Keefe F.J., et al. (2000). The relationship of daily mood and stressful events to symptoms in juvenile rheumatic disease. *Arthritis Care and Research,* (13): 33-41.

Scholz J., & Woolf C.J. (2002). Can we conquer pain? *Nature Neuroscience Supplement,* 5: 1062-1067.

Souffrir, ça fait plus mal quand on y pense. Université de Montréal. iForum 40(6) (October 2005). Retrieved November 1st, 2005 from http://www.iforum.umontreal.ca/Forum/20052006/20051003/souffrir.html. Last updated February 27th, 2006.

Stanos S., & Houle T.T. (2006). Multidisciplinary and interdisciplinary management of chronic pain. *Physical Medicine and Rehabilitation Clinics of North America,* 17: 435-459.

Strong J., Ashton R., Cramond T., Chant D. (1990). Pain intensity, attitude and function in back pain patients. *The Australian Occupational Therapy Journal,* 37(4): 179-183.

Sullivan M.J., Lynch M.E., Clarck A.J. (2005). Dimensions of catastrophizing thinking associated with pain experience and disability in patients with neuropathic pain conditions. *Pain,* 113: 310-315.

Sullivan M.J., Reesor K., Mikail S., Fisher R. (1992). The treatment of depression in chronic low back pain: review and recommendations. *Pain,* 50: 5-13.

Sullivan M.J., Thorn B., Haythornthwaite J.A., Keefe F., Martin M., Bradley L.A., et al. (2001). Theoretical perspectives on the relation between catastrophizing and pain. *The Clinical Journal of Pain,* 17(1): 52-64.

Swinkels-Meewisse I.E., Roelofs J., Schouten E.G., Verbeek A.L., Oostendorp R.A., Vlayen J.W. (2006). Fear of movement/(re)injury predicting chronic disabling low back pain: a prospective inception cohort study. *Spine,* 31(6): 658-664.

Swiontkowski M.F., Engelberg R., Martin D.P., Agel J. (1999). Short musculoskeletal function assessment questionnaire: validity, reliability, and responsiveness. *The Journal of Bone and Joint Surgery,* 81-A(9): 1245-1260.

Tait R.C., & Chibnall J.T. (1997). Development of a brief version of the Survey of Pain Attitudes. *Pain,* 70: 229-235.

Tait R.C., Chibnall J.T., Krause S. (1990). The Pain Disability Index: psychometric properties. *Pain,* 40: 171-182.

Thomas J.S., France C.R., Lavender S.A., Johnson M.R. (2008). Effects of fear of movement on spine velocity and acceleration after recovery from low back pain. *Spine,* 33(5): 364-370.

Thorn B.E., Ward L.C., Sullivan M.J.L., Boothby J.L. (2003). Communal coping model of catastrophizing: conceptual model building. *Pain,* 106: 1-2.

Tremont-Lukats I.W., Teixeira G.M., Bakonja M.M. (2003). Systemic lidocaine and local anesthetic-type drugs for neuropathic pain (Protocol for a Cochrane Review). In: *The Cochrane Library.* Issue 3. Oxford: Update Software.

Turner J., Brister H., Aaron L., Mancl L., Huggins K., Truelove E. (2005). Association of self-efficacy with pain, functioning, and coping among patients with temporomandibular disorder pain. *The Journal of Pain,* 6(3) Suppl.1: S57.

Turner J.A., Jensen M.P., Romano J.M. (2000). Do beliefs, coping, and catastrophizing independently predict functioning in patients with chronic pain? *Pain,* 85: 115-125.

Unruh A.M. (1996). Gender variations in clinical pain experience. *Pain,* 65: 123-167.

Vase L., Robinson M.E., Verne G.N., Price D.D. (2003). The contributions of suggestion, desire, and expectation to placebo effects in irritable bowel syndrome patients An empirical investigation. *Pain,* 105(1-2): 17-25.

Villemure C., & Bushnell CM. (2002). Cognitive modulation of pain: how do attention and emotion influence pain processing? *Pain,* 95: 195-199.

Vlaeyen J.W.S., Kole-Snijders A.M.J., Boeren R.G.B., van Eek H. (1995). Fear of movement/(re)injury in chronic low back pain and its relation to behavioural performance. *Pain,* 62: 363-372.

Waddell G., Newton M., Henderson I., Somerville D., Main C.J. (1993). A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain,* 52: 157-168.

Walters S.J., & Brazier J.E. (2003). What is the relationship between the minimally important difference and health state utility values? The case of the SF-6D. *Health and Quality of Life Outcomes,* 1: 4.

Warfield C.A., & Fausett H.J. (2002). *Manual of Pain Management.* 2nd ed. Philadelphia: Lippincott Williams & Wilkins.

Williams D.A., & Thorn B.E. (1989). An empirical assessment of pain beliefs. *Pain,* 36: 351-358.

Woby S.R., Urmston M., Watson P.J. (2007). Self-efficacy mediates the relation between pain-related fear and outcome in chronic low back pain patients. *European Journal of Pain,* 11(7): 711-718.

Woolf C.J., & Wiesenfeld-Hallin Z. (1985). The systemic administration of local anesthetics produces a selective depression of C-afferent fibre evoked activity in the spinal cord. *Pain,* 23: 361-374.

APPENDICES

Appendix 1: List of the variables and outline of the measurement strategy.

Variable	Definition	Type	Instrument	Scale
Exposure				
Decrease on no decrease in pain intensity due to LI.	≥ 28mm or 33% decrease on VAS between the day of the LI and 4 days post-infusion.	Exposure	VAS	Dichotomous (decreased or not decreased)
First time or repeat LI user.	Already received LI or not?	Exposure	Data Form	Dichotomous (yes or no)
Outcome				
Functional status.	The subject's perception of their functional performance.	Outcome	SMAF	Continuous (0 to 100 for each Index, in decimals)
Beliefs and attitudes towards pain.	7 categories of beliefs and attitudes concerning pain considered critical for adjustment to long term chronic pain.	Outcome	SOPA-32	Ordinal (0 to 4 for each of the 7 categories, in decimals)
Pain intensity	At 14 days and 2 to 3 weeks post-infusion.	Outcome	VAS	Continuous (0 to 100mm, in decimals)
Socio-demographic confounders				
Age	In years	Confounder	Data form	Ordinal (number of years)
Gender	Male or female	Confounder	Data form	Dichotomous (M or F)
Education level	Highest education level completed.	Confounder	Data form	Dichotomous (high school or under / more than high school)
Marital status	Single, married, separated, divorced, cohabitation or widow.	Confounder	Data form	Dichotomous (married or cohabitation / single, separated, divorced or widow)
Employment status	Currently working or not?	Confounder	Data form	Nominal (yes, no because of pain, no for other reasons than pain)
Compensation status	Currently receiving a disability income or not?	Confounder	Data form	Dichotomous (yes or no)
Pain-related confounders				
Pain intensity (pre infusion)	Pain intensity before the LI	Confounder	VAS	Continuous (0 to 10 cm in decimals)
Duration of pain	In months	Confounder	Data form	Ordinal (number of months)
Localization of pain	Head, neck, back, upper or lower extremity, or other.	Confounder	Data form	Nominal (Head / neck / back / upper extremity / lower extremity or other)
Number of painful sites	3 or less or more than 3.	Confounder	Data form	Dichotomous (3 or less / more than 3)
Circumstance of pain onset	Accident, illness, surgery or no identifiable cause.	Confounder	Data form	Nominal (accident / illness or surgery / no identifiable cause)
Use of opioids	Yes or no.	Confounder	Data form	Dichotomous (yes or no)
Current treatments	Interventions actually given at the Pain Centre or somewhere else.	Confounder	Data form	Nominal (medication / nerve or venous blocks / individual psychology counseling, support group, education / physiotherapy / radiofrequency, TENS, neurostimulator / osteopathy, acupuncture, massotherapy)

APPENDIX 2: GEN-Research Ethics Board approval

Centre universitaire de santé McGill
McGill University Health Centre
Les meilleurs soins pour la vie
The Best Care for Life

McGill University Health Centre
Genetics/Population Research
Investigator Initiated Studies
Research Ethics Board

DEC 04 2006

DATE OF APPROVAL

December 4, 2006

Ms. Julie Masse
Occupational Therapist
McGill University Health Centre

RE: **GEN#06-028 entitled "Associations between Decreased Pain Intensity, Functional Status and Beliefs and Attitudes towards Pain in People with Chronic Pain after Lidocaine Infusion."**

Dear Ms. Masse:

The research proposal entitled above received Full Board review at the convened meeting of the MUHC-Montreal General Hospital Research Ethics Committee on September 5, 2006, and was entered accordingly into the minutes of the Research Ethics Board (REB) meeting.

We are writing to inform you that the above referenced study was found ethically acceptable for conduct at the McGill University Health Centre, and we hereby grant you full approval, via review of the Co-Chair on December 4, 2006, for the research protocol (dated September 5, 2006), the revised English and French Consent Documents (dated October 12, 2006), the English and French letters to participants, and the English and French questionnaires.

At the MUHC, sponsored research activities that require US federal assurance are conducted under Federal Wide Assurance (FWA) 00000840.

All research involving human subjects require review at a recurring interval and the current study approval is in effect until **September 5, 2007**. It is the responsibility of the principal investigator to submit an Application for Continuing Review to the REB prior to the expiration of approval to comply with the regulation for continuing review of "at least once per year".

It is important to note that validation for the translated version of the consent document has been certified by an MUHC translator. Any further modification to the REB approved and certified consent document must be identified by a revised date in the document footer, and re-submitted for review prior to its use.

The Research Ethics Boards (REBs) of the McGill University Health Centre are registered REBs working under the published guidelines of the Tri-Council Policy Statement, in compliance with the "Plan d'action ministériel en éthique de la recherche et en intégrité scientifique" (MSSS, Qc) and the Food and Drugs Act (17 June, 2001); and acting in conformity with standards set forth in the (US) Code of Federal Regulations governing human subjects research, functions in a manner consistent with internationally accepted principles of good clinical practice.

We wish to advise you that this document completely satisfies the requirement for Research Ethics Board Attestation as stipulated by Health Canada.

HÔPITAL GÉNÉRAL DE MONTRÉAL • MONTREAL GENERAL HOSPITAL
1650, avenue Cedar, Montréal (Québec) Canada H3G 1A4, Tél: (514) 934-1934

APPENDIX 6: Consent Form

Centre universitaire de santé McGill
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Les meilleurs soins pour la vie
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ASSOCIATIONS BETWEEN
PAIN INTENSITY, FUNCTION AND ATTITUDES TOWARDS PAIN
IN PEOPLE WITH PERSISTING PAIN
AFTER A LIDOCAINE INFUSION

McGill University Health Centre
Genetics/Population Research
Investigator Initiated Studies
Research Ethics Board
DEC 0 6 2006
DATE OF APPROVAL

Investigators

Julie Masse, Occupational Therapist, Master's Degree Student, McGill School of Physical and Occupational Therapy.

Patricia McKinley, Associate Professor, McGill School of Physical and Occupational Therapy.

Ann Gamsa, Associate Director, Director Psychological Service, MUHC Pain Centre.

Yoram Shir, Clinical Director, MUHC Pain Centre.

Introduction

You are being asked to participate in this study because you will be receiving a lidocaine infusion for localized pain at a specific site on your body.

Before deciding to participate in the study, you should clearly understand its requirements, risks and benefits. This document provides information about the study, and it may contain words you do not fully understand. Please read it carefully and ask the researcher any questions you may have. She will discuss the study with you in detail. You may discuss the study with anyone else before making your decision. If you decide to participate, you will be asked to sign this form and a copy will be given to you.

Purpose of the Study

The purpose of this study is to look at the associations between pain, function and attitudes towards pain following a lidocaine infusion.

Description of the Study

In addition to the usual procedure for a lidocaine infusion, this study requires you to complete a battery of questionnaires. The day of the infusion, before you receive the infusion, you will be meeting the investigator to complete the data form about your personal characteristics and your own pain problem. At that time, you will also rate your pain intensity and complete two questionnaires about your daily functioning and you attitudes towards pain. Four days after the lidocaine infusion, you will rate your pain intensity at home on a sheet of paper. At fourteen days and again at twenty-one days after the infusion, you will have to rate your pain intensity and also complete the two questionnaires at home. After completing the questionnaires, you will place them into an envelope given to you by the investigators and

seal and date the envelope. The investigator will contact you on the phone each day you are scheduled to complete the questionnaires. Finally, you will have to bring back the completed questionnaires at the follow up visit with your doctor. If you do not agree to be part of the study, you will be asked to allow the research team to collect data from your medical chart relating to your pain.

Risks and Discomforts

The principal disadvantage of participating in this study is the time required to fill out the questionnaires. You will not have to come more often to the Pain Centre than what is usually required when receiving a lidocaine infusion, but you will have to come sooner (45 minutes) the day of the infusion. You will also have to take a few minutes (approximately 22 minutes) to complete the questionnaires twice at home. You will also have to bring back the questionnaires at the follow up visit.

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Potential Benefits

You should not expect any direct benefits from participating in this study. However, the information collected from this study may benefit future patients by helping us to better understand the associations between pain, function and attitudes towards pain following a lidocaine infusion. It may provide ideas on how to improve services for people with pain problems.

Cost and Compensation

You will not be offered any compensation for your participation in this study.

Confidentiality

The researcher will consult you medical chart for information relevant to this study. All information obtained during this study will be kept strictly confidential. Your name will be coded and the code list will be locked in a filing cabinet in the investigator's office with limited access. The results from this study may be published, but your identity will not be revealed in the combined results. In order to verify the research study data, representatives from one of the McGill University Health Centre Research Ethics Boards may review these records.

By signing this consent form, you give us permission to release information regarding your participation in this study to these entities, and to inform your treating physician of your participation in this research study. Your confidentiality will be protected to the extent permitted by applicable laws and regulations.

Voluntary Participation and/or Withdrawal

Your participation in this study is strictly voluntary. You may refuse to participate or may discontinue your participation at any time without explanation, and without penalty. If you decide not to participate, or if you discontinue your participation, your medical care will in no way be affected nor your participation in any other research studies. The investigators or clinical health professionals may end your participation in the study if it is felt to be in your best interest.

APPENDIX 7: Formulaire de consentement

Centre universitaire de santé McGill
McGill University Health Centre
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ASSOCIATIONS ENTRE L'INTENSITÉ DE LA DOULEUR, LA FONCTION ET LES ATTITUDES ENVERS LA DOULEUR CHEZ LES PERSONNES AVEC DES PROBLÈMES DE DOULEUR CHRONIQUE APRÈS UNE INFUSION DE LIDOCAÏNE.

Investigateurs

Julie Masse, ergothérapeute, étudiante à la maîtrise, École de physiothérapie et d'ergothérapie de l'Université McGill.

Patricia McKinley, Professeur associée, École de physiothérapie et d'ergothérapie de l'Université McGill.

Ann Gamsa, Directrice associée, Directrice du service de psychologie, Centre de la douleur du Centre Universitaire de santé McGill.

Yoram Shir, Directeur clinique, Centre de la douleur du Centre Universitaire de santé McGill.

McGill University Health Centre
Genetics/Population Research
Investigator Initiated Studies
Research Ethics Board
DEC 04 2006
DATE OF APPROVAL

Introduction

On vous a offert de participer à cette recherche puisque vous allez recevoir une infusion de lidocaine pour votre douleur localisée à un endroit spécifique de votre corps.

Avant de décider si vous participerez à cette étude, vous devez comprendre clairement ses conditions, ses risques et bénéfices. Ce document vous offre de l'information à propos de cette étude et pourrait contenir des mots qui ne vous sont pas familiers. Veuillez, s'il vous plait, le lire attentivement et faire part de la moindre interrogation à l'investigatrice qui saura répondre à vos questions. Vous pouvez discuter de cette étude avec d'autres personnes avant de prendre votre décision. Si vous décidez d'y participer, nous vous demanderons de signer ce formulaire et une copie vous sera remise.

But de la recherche

Le but de cette étude est d'étudier les associations entre la douleur, la fonction et les croyances et attitudes envers la douleur suite à une infusion de lidocaïne.

Description de la recherche

En plus des procédures habituelles entourant une infusion de lidocaïne, nous vous demanderons de compléter des questionnaires. Avant l'infusion, une investigatrice vous rencontrera afin de vous aider à remplir un formulaire de données décrivant vos caractéristiques personnelles et votre problème de douleur. À ce moment, vous coterez l'intensité de votre douleur et compléterez deux questionnaires concernant votre fonctionnement quotidien et vos attitudes envers la douleur. Quatre jours après l'infusion de lidocaine, vous coterez l'intensité de votre douleur sur une feuille de papier à la maison. Quatorze jours et vingt et un jours après l'infusion, vous aurez de nouveau à évaluer l'intensité de votre douleur et aussi à compléter les deux questionnaires à la maison. Après avoir complété ces questionnaires, vous les placerez dans une enveloppe qui vous aura été remise par une investigatrice. Vous scellerez l'enveloppe et y inscrirez la date. L'investigatrice vous contactera par téléphone le jour

précédant les jours où vous aurez à compléter les questionnaires. Finalement, vous aurez à rapporter les questionnaires complétés à la rencontre de suivi avec votre médecin. Si vous décidez de ne pas participer à cette étude, nous vous demanderons de permettre aux investigateurs de recueillir des informations de votre dossier médical concernant votre problème de douleur.

Risques et inconforts

Le principal désavantage à participer à cette recherche est le temps requis pour remplir les questionnaires. Vous n'aurez pas à vous présenter au Centre de la douleur plus souvent que ce qui est normalement requis pour recevoir une infusion de lidocaine mais il vous faudra arriver 45 minutes plus tôt le jour de l'infusion. Vous aurez également à prévoir quelques minutes (environ 22 minutes) pour compléter les questionnaires à deux reprises à la maison. Aussi, vous devrez rapporter les questionnaires au rendez-vous de suivi.

Bienfaits potentiels

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Vous ne devriez vous attendre à aucun bénéfice direct de votre participation à cette étude. Cependant, l'information recueillie par cette recherche pourrait bénéficier à de futurs patients en nous aidant à mieux comprendre les associations entre la douleur, la fonction et les attitudes envers la douleur après une infusion de lidocaïne. Cela pourrait nous donner des pistes pour améliorer les services pour les personnes avec des problèmes de douleur.

Coûts et compensation

Vous ne recevrez aucune compensation pour votre participation à cette recherche.

Confidentialité

L'investigatrice consultera votre dossier médical pour des informations utiles à cette étude. Toute l'information obtenue durant cette recherche sera gardée de façon strictement confidentielle. Votre nom sera codé et la liste des codes sera conservée sous clef dans une filière au bureau des investigateurs avec accès limité. Les résultats de cette recherche pourront être publiés, mais votre identité ne sera pas révélée dans les résultats combinés. Afin de vérifier les données de cette recherche, des représentants d'un des Bureau d'éthique de recherche du Centre Universitaire de Santé de McGill pourront réviser ces dossiers.

En signant ce formulaire de consentement, vous nous donnez la permission de communiquer l'information relative à votre participation à cette recherche aux organismes énumérés précédemment et d'informer votre médecin traitant de votre participation à cette recherche. Votre confidentialité sera protégée en respect des lois et règlements applicables.

Participation volontaire et/ou retrait

Votre participation à cette recherche est strictement volontaire. Vous pouvez refuser de participer et cesser votre participation à tout moment sans explication et sans pénalité. Si vous décidez de ne pas participer ou si vous cesser votre participation, vos soins médicaux ne seront en aucun cas affectés ainsi que votre participation à toute autre recherche. Les investigateurs et le personnel soignant pourraient mettre fin à votre participation si cela semblait être dans votre meilleur intérêt.