Clinicians are facing increased pressure from medical funders and peer review groups to treat patients according to “Evidence Based Medicine” criteria. This has often been labeled as “Best Practice”. The principles involved in this form of practice are correct but in many circumstances no such criteria have been determined. Cynics will correctly state that evidence based medicine is sometimes based on no evidence at all. Despite this, funders will often refuse a form of therapy as there is “no evidence that it works”. This decision is frequently made by non-medical personnel who are simply following a sometimes arbitrary algorithm.

The Executive of PAINSA has committed itself to develop series of algorithms for the various pain conditions that are frequently seen by clinicians. I intend to publish these recommendations and request that the various role players who treat pain sufferers comment on these suggestions so that ultimately a consensus guideline can be produced and published. You will note that I have not called the preliminary document a guideline but rather a recommendation as you are all aware that pain therapy is multidisciplinary and that all the concerned clinicians must supply input before such a recommendation can be called a guideline. The final guideline will not be the opinion of one individual or one group of specialists but rather a consensus statement of all the groups of clinicians who treat a specific type of pain.

This edition contains a letter from Dr CN De Villiers who has submitted “his guidelines” for the treatment of chronic spinal pain. It is fairly comprehensive and includes standard definitions and treatment algorithms. He has included his opinion on suggested fees for such procedures as well as relevant treatment codes from the SAMA Guide to Billing. It does not have a comprehensive list of references that validate his suggestions nor is there any “evidenced based” data. Despite these omissions it serves as a working document and I thank him for his input and suggestions. Your comments and suggestions are necessary to improve this document.

I have also included suggested guidelines for the physiotherapists compiled by Ms Phyllis Berger who is a member of the PAINSA executive committee and a member the editorial board of this journal. This well researched and referenced document is very comprehensive. Prior to publishing this document as a definitive guideline I would request that all interested role players offer comment and suggestions pertaining to this document.

Finally I would like to introduce a new addition to my editorial board. She is Dr Eva Frolich. Eva is an anaesthesiologist and is the principal specialist at Coronation and Helen Joseph Hospitals where she has been running a chronic pain clinic. Eva has a Masters degree in pain management from the University of Sydney. I am sure she will make a meaningful contribution to this journal.

Dr. Milton Raff  
BSc (WITS), MBChB (Pret), FFA (SA)
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PAIN TOP25 articles within the journal pain

Case Report: Special Reports – Peripheral Nerve Stimulation

Use of a peripheral nerve stimulator for intractable chronic pain

Dr Milton Raff

Letters to the editor: Guidelines for the management of chronic spinal pain

Dr N de Villiers

Suggested Guidelines:

Physiotherapy Management of Chronic Low Back Pain: Non-pharmacological management

Phyllis Berger

Psychological Interventions for Acute and Chronic Pain in Children

Christina Liossi

Pain affects spouses too: Personal experience with pain and catastrophizing as correlates of spouse distress

Michelle T. Leonard, Annmarie Cano

Efficacy and safety of a single botulinum type A toxin complex treatment (Dysport) for the relief of upper back myofascial pain syndrome: Results from a randomized double-blind placebo-controlled multicentre study

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   Pain, Volume 123, Issue 3, 1 August 2006, Pages 226-230
   Diatchenko, L.; Nackley, A.G.; Slade, G.D.; Fillingim, R.B.; Maixner, W.

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   Ho, K.Y.; Gan, T.J.; Habib, A.S.

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   Kidd, B.L.

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   Pain, Volume 123, Issue 3, 1 August 2006, Pages 231-243

6. Mechanisms underlying development of spatially distributed chronic pain (fibromyalgia) • Review article
   Pain, Volume 124, Issue 3, 1 October 2006, Pages 242-263
   Vierck, C.J.

7. Site-specific increases in peripheral cannabinoid receptors and their endogenous ligands in a model of neuropathic pain • Article
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8. Efficacy of pregabalin in neuropathic pain evaluated in a 12-week, randomised, double-blind, multicentre, placebo-controlled trial of flexible- and fixed-dose regimens • Article
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   Vassiliou, T.; Kaluza, G.; Putzke, C.; Wulf, H.; Schnabel, M.

10. Mechanical sensory threshold testing using nylon monofilaments: The pain field’s”Tin Standard” • Review article
    Pain, Volume 124, Issue 1-2, 1 September 2006, Pages 13-17
    Bove, G.

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    Feuerstein, M.; Hartzell, M.; Rogers, H.L.; Marcus, S.C.

12. Duloxetine vs. placebo in patients with painful diabetic neuropathy • Article
    Pain, Volume 116, Issue 1-2, 1 July 2005, Pages 109-118
    Goldstein, D.J.; Lu, Y.; Detke, M.J.; Lee, T.C.; Iyengar, S.
13. The role of pain coping strategies in prognosis after whiplash injury: Passive coping predicts slowed recovery • Article
Pain, Volume 124, Issue 1-2, 1 September 2006, Pages 18-26
Carroll, L.; Cassidy, J.D.; Cote, P.

14. Pregabalin for the treatment of painful diabetic peripheral neuropathy: a double-blind, placebo-controlled trial • Article
Pain, Volume 110, Issue 3, 1 August 2004, Pages 628-638
Rosenstock, J.; Tuchman, M.; LaMoreaux, L.; Sharma, U.

15. Epidemiology and treatment of neuropathic pain: The UK primary care perspective • Article
Pain, Volume 122, Issue 1-2, 1 May 2006, Pages 156-162
Hall, G.C.; Carroll, D.; Parry, D.; McQuay, H.J.

16. Multiple pathways for noxious information in the human spinal cord • Article
Pain, Volume 123, Issue 3, 1 August 2006, Pages 322-331

17. A randomized, double-blind, placebo-controlled trial of duloxetine in the treatment of women with fibromyalgia with or without major depressive disorder • Article
Pain, Volume 119, Issue 1-3, 1 December 2005, Pages 5-15
Arnold, L.M.; Rosen, A.; Pritchett, Y.L.; Di'Souza, D.N.; Goldstein, D.J.; Iyengar, S.; Wernicke, J.F.

18. Depletion of endogenous spinal 5-HT attenuates the behavioural hypersensitivity to mechanical and cooling stimuli induced by spinal nerve ligation • Article
Pain, Volume 123, Issue 3, 1 August 2006, Pages 264-274
Rahman, W.; Suzuki, R.; Webber, M.; Hunt, S.P.; Dickenson, A.H.

19. Signaling pathway of morphine induced acute thermal hyperalgesia in mice • Article
Pain, Volume 123, Issue 3, 1 August 2006, Pages 294-305
Galeotti, N.; Stefano, G.B.; Guarna, M.; Bianchi, E.; Ghelardini, C.

20. CB2 cannabinoid receptor mediation of antinociception • Article
Pain, Volume 122, Issue 1-2, 1 May 2006, Pages 36-42
Ibrahim, M.M.; Rude, M.L.; Stagg, N.J.; Mata, H.P.; Lai, J.; Vanderah, T.W.; Porreca, F.; Buckley, N.E.; Makriyannis, A.; Malan, T.P.

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Colloca, L.; Benedetti, F.

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Wijnhoven, H.A.H.; de Vet, H.C.W.; Picavet, H.S.J.

23. Pain activates cortical areas in the preterm newborn brain • Article
Pain, Volume 122, Issue 1-2, 1 May 2006, Pages 109-117
Bartocci, M.; Bergqvist, L.L.; Lagercrantz, H.; Anand, K.J.S.

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Pain, Volume 123, Issue 3, 1 August 2006, Pages 275-284
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CASE REPORT
Special Reports – Peripheral Nerve Stimulation
Use of a peripheral nerve stimulator for intractable chronic pain

Dr Milton Raff  BSc (Wits), MBChB (Pret), FFA (SA)

The following article by Dr. Milton Raff (Pain Unit, Christiaan Barnard Memorial Hospital, Cape Town, South Africa) outlines a clinical case study in which peripheral nerve stimulation was successfully used for the treatment of intractable chronic pain.

History

The patient, a 35-year old Caucasian male with no previous medical history, first underwent surgery eight years ago for relief of typical ulnar nerve entrapment symptoms in his left arm. The surgical procedure was uneventful and to date he remains cured from his symptoms. Shortly afterwards the patient began to experience similar symptoms in his right arm and a similar procedure was performed on his right side (i.e. ulnar nerve neurolysis). However, although the procedure was uneventful, the pain was not relieved, if anything, being slightly worse. The patient then underwent a second ulnar nerve neurolysis and transposition of the nerve. Once again, his symptoms were not relieved and the pain worsened. A full neurological assessment, including electromyographical studies, confirmed that the lesion was located in the ulnar nerve distribution. Further surgical procedures included exploration of the ulnar nerve at the elbow, a Guyon’s tunnel release, and a thoracic outlet exploration including brachial plexus neurolysis and first rib resection, none of which provided relief from the pain.

The history and symptomatology clearly indicated that the pain was neuropathic in nature, i.e. resulting from damage to nerve fibres. Further surgical interventions were not anticipated as they were unlikely to improve the situation; indeed, it was thought that surgery would actually worsen the situation. Treatment with primary analgesics also failed to relieve the pain.

The patient consulted a psychiatrist to seek help in managing a normal lifestyle. However, psychotherapy did nothing to relieve his pain. In desperation the patient was referred to a pain clinic.

Management

Following extensive discussions with the patient, it was decided to begin therapy using a tricyclic antidepressant, amitryptaline (25 mg administered at night), together with an antiepileptic, gabapentin (1200 mg administered daily). This medication was to be taken in conjunction with primary analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs). However, this regime resulted in no improvement in the pain.

It was clear that the pain was confined to the area of distribution of the ulnar nerve since the median and radial nerves exhibited a normal profile of sensory and motor nerve conduction. The fundamental problem remained of how to relieve neuropathic pain resulting from a scarred and entrapped nerve. The scarring was located in the mid-humeral region. As a diagnostic test, 3 ml of a 2% lidocaine solution was injected around the ulnar nerve proximal to the surgical scar. Identification of the nerve was facilitated using an electrical current and a sheathed stimulating catheter (Stimuplex, B Braun). Total pain relief was observed for the duration of the action of lidocaine.

Although permanent block of the ulnar nerve at this site would relieve the pain, this is not favourable as a result of the associated loss of motor function that would be observed in all the distal muscles innervated by this nerve. However, an article published in Plastic and Reconstructive Surgery on peripheral nerve stimulators offered a possible solution. The peripheral nerve stimulator delivers an electrical stimulation directly onto a peripheral nerve, the effect of which is to stimulate sensory nerve fibres conducting pain while not affecting motor fibres. This is achieved by using low-voltage high-frequency stimulation.

In the absence of a successful pain therapy, the patient was willing to have a peripheral nerve stimulator implanted.
Procedure

The insertion of the Medtronic peripheral nerve stimulator (Synergy) was performed as a two-stage procedure. The first stage involved the insertion of the peripheral stimulating lead. The incision on the patient’s arm was extended proximally to expose the ulnar nerve. The degree of adhesion around the distal section of the nerve was clearly evident. The proximal section of the nerve appeared normal, and the stimulating lead was inserted adjacent to the nerve at this region. The conducting lead was tunneled subcutaneously in a proximal direction and then exteriorized. All the incisions were then closed. The lead was attached to a temporary nerve stimulator and with the cooperation of the patient the frequency and amplitude of the stimulation were adjusted until the patient experienced total pain relief.

The settings were maintained and the response of the patient noted. Occasionally, the stimulator was switched off without the knowledge of the patient and the response was noted. In this mode, the patient immediately detected the change as a return of his pain. After one week, during which the patient experienced total pain relief, the second stage of the implantation process was undertaken.

The second stage of the procedure consisted of tunneling a permanent electrode between a pocket created on the anterior chest wall and the stimulating lead. The lead was connected to the permanent Medtronic stimulator, which was then inserted into the pocket. All skin incisions were sutured. The settings of the permanent stimulator were identical to that of the temporary module. However, if required, an external programmer could be used to alter these settings in order to optimize analgesia.

Results

At 8 weeks the patient had not experienced any pain or adverse side-effects. Furthermore, he had not needed any supplementary analgesia and had returned to work and resumed his normal lifestyle. The patient was seen 2–3 months ago and was pain free and functioning normally.

Discussion

In this patient the compressed ulnar nerve was responsible for the pain. All of the ulnar nerve fibres were compressed, however, the symptoms manifested as pain rather than muscle weakness or atrophy. The Aβ, Aδ and C nerve fibres in the ulnar nerve are responsible for transmitting pain impulses to the dorsal horn of the spinal cord. The Medtronic Synergy peripheral nerve stimulator selectively stimulated these fibres using a low-voltage high-frequency voltage so that the ‘fast’ fibre impulses would block the entry of the ‘slow’ fibre impulses into the spinal cord. Because the ‘slow’ fibres transmit the noxious painful stimuli the pain response was therefore reduced. This mode of action is based on the principle of the ‘gate theory’ of pain.

This case study demonstrates that the Medtronic Synergy peripheral nerve stimulator is a useful adjunct for the pain specialist, particularly when confronted with a patient suffering from chronic intractable neuropathic pain.

References

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Letters to the Editor:
GUIDELINES FOR THE MANAGEMENT OF CHRONIC SPINAL PAIN

These are my suggested guidelines for the management of chronic spinal pain. Your comments and those of the readers will be appreciated.

Dr Neels de Villiers
MB MBCh (Wits Univ), FRCS (Edin), FRCS (Glas) FIPP (USA)

1. Definitions:

1.1 Acute back/neck pain is pain lasting less than 3 months from time of onset (not time of consultation).

1.2 Chronic back/neck pain is pain lasting more than 3 months from time of onset (not time of consultation).

1.3 Diagnostic blocks are local anaesthetic blocks that are used in a reductionist way to identify the specific pain generator. Only then is definitive treatment e.g. radiofrequency or nerve sleeve block applied.

Diagnostic blocks consist of facet (intra-articular) blocks; median facet nerve blocks (branch blocks); s.i. joint blocks, provocative discography or epidural injections.

1.4 Non-specific spinal or somatic spinal pain
This is pain that is due to any other cause other than by spinal nerve compression (nerve root compression by disc herniation).
Non-specific back/neck pain is responsible for 80 – 85% of all chronic back/neck pain1.

2. Acute back or neck pain (Lasting less than 3 months)

2.1 Methodology
Exclude radicular pain due to disc herniation - i.e. nerve root compression.
Identify the specific pain generator - i.e. facet joint disc or S.I. joint, by following flow chart (see Figure 1).
Once pain generator is identified - i.e. pain is relieved, stop process.
If no pain generator is identified, complete process with transforaminal epidural injection.

Figure 1
3. Spinal facet blocks / S.I. joint injections / discography

3.1 **Indications**: To relieve acute spinal pain from non-radicular origin lasting less than 3 months.

3.2 **Contra-indications**
- Infection at the site / systemic infection i.e. bacteremia.
- Patient on warfarin.
- Allergy to injecting agent (iodine in discography)

3.3 **Equipment**
- 25 gauge needle for skin infiltration.
- 22 gauge (black), 150mm spinal needle.

3.4 **Drugs**
- 0.5% Ropivacaine
- 2% Lidocaine
- Tramcinolone diacetate

3.5 **Location / logistics**
- Sterile procedure room & c-arm.
- Neurolept anaesthetic is optional.


3.7 Follow up at / or before 6 weeks to prevent chronicity

4. Chronic back/neck (spinal) pain
This is due to somatic (non-radicular) pain lasting more than 3 months. Chronic spinal pain is only 5% of the total spinal pain population, but chronic spinal pain is responsible for 80% of the expenses for treating all back/neck pain. It is here where percutaneous radiofrequency thermo-aglutination (neurolysis) comes into its own.

4.1 **Methodology**
Exclude radicular pain (nerve root compression) due to disc herniation. Identify the specific pain generator – i.e. facet joint (35% - 40)% of cases) ; disc (20 – 25% of cases) or S.I. joint (30% - 35% of cases) by doing diagnostic blocks following flow chart (see Figure 2). If the pain generator was identified 4 – 6 weeks earlier following this technique then proceed directly to radiofrequency neurolysis of the facet. If no pain generator has been identified, complete processes with transforaminal or caudal epidural injection.

**Figure 2**

Chronic low back pain

Somatic Pain

i. Facet joint pain
   Intraradicular
   Facet joint blocks
   Medial branch blocks or Radiofrequency
ii. S.I. Joint Pain
   S.I. joint blocks
iii. Discogenic Pain
   Intradiscal therapy

Radicular Pain

i. No Surgery / Post Surgery / Spinal Stenosis
   Step i: Caudal/Interlaminar
   or Transforaminal epidural
   Step ii: Percutaneous Adhesiolysis
ii. No Surgery
   Step iii: Discography and Intradiscal therapy
iii. Post Surgery
   Step iv: Spinal Endoscopic Adhesiolysis
   Step v: Implantable therapy
4.2 **Indications for back/neck radiofrequency (RF) facet neurolysis**
To relieve chronic spinal pain from non-radicular origin lasting more than 3 months – i.e. chronic pain.

4.3 **Contra-indications**
- Infection at the site/systemic infection bacteremia.
- Patient on Warfarin ; patient with a pacemaker.
- Allergy to injecting agent (iodine)
- Psychogenic patient.

4.4 **Equipment**
- Radiofrequency thermo-coagulation machine and electrode; discography machine
- 20 gauge, 10cm radiofrequency needle with 10mm active tip (1 needle per site)
- 25 gauge needle for skin infiltration prior to introducing radiofrequency needle.

4.5 **Location/logistics**
- Sterile procedure room with c-arm.
- Neurolept anaesthetic (not general anaesthetic).

4.6 **Technique**

4.7 **Follow up**
- at 3 – 6 weeks to determine outcomes of procedure.

4.8 **Efficacy**
- of facet (medial branch) radiofrequency neurolysis is 85% pain relief at 12 months.

4.9 **Codes and payment**
I suggest the following code/payment.

- Since the median facet nerve supplies the joint at its particular level and gives a branch to the facet joint below on the same side, it is international practise to do 2 joints on the left and 2 joints on the right, since mechanical back pain radiates from side to side. For these 4 medial branch radiofrequency procedures with 4 radiofrequency needles, I suggest “1 code - 1 fee” – i.e. :

- Code 2927 and a flat fee of R3 200.00.

This will detract from doing 6 – 8 levels.

If an extra site – i.e. neck pain and back pain are done, then 4 procedures in the neck will be billed as :

- Code 2927 neck  R3 200.00 (4 needles)
- Code 2927 back  R3 200.00
- R6 400.00 Total for 2 problems

Radiofrequency should only be performed once per year since in 85% of cases pain will be relieved for at least 1 year.

I hope you find this protocol helpful. I have been using it for 8 years with success.

Kind regards

Dr Neels de Villiers  
MB.BCh (Wits Univ), FRCS (Edin), FRCS (Glas.) FIPP (USA)
Success is built on a solid clinical foundation.

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There are many factors that create difficulties in developing physiotherapy guidelines for chronic low back pain. One of the difficulties in generalizing results across studies is that outcome measures are often not comparable and may not permit general conclusions (Nielson and Weir, 2001). A systematic review of Exercise Therapy for Low Back Pain within the framework of the Cochrane Collaboration Back Review Group concluded that exercises may be helpful for patients with chronic low back pain to increase return to normal daily activities and work (van Tulder et al 2000). Many studies of physical treatments for chronic low back pain have not produced conclusive results including a RCT of physiotherapy compared with advice for low back pain concluding that physiotherapy was no more effective than one session of assessment and advice from physiotherapists (Frost et al. 2004). The general lack of exercise treatment specificity suggests that the main effects of therapeutic exercise are produced not through the reversal of physical weaknesses targeted by the corresponding exercise but rather through some ‘central’ effect perhaps involving an adjustment of perception in relation to pain and disability (Mannion A et al. 1999). However it is now acknowledged that the use of physiotherapy in the multidimensional context has proved the more appropriate model due to the complexity of the development of pain and its presentation in many circumstances (Waddell, 1992). Fordyce produced a therapeutic approach to the behavioural management of pain (Fordyce, 1976), especially when pain is not viewed as a symptom of tissue damage alone and Turk applied these cognitive principles in 1983 (Turk, Meichenbaum and Genest, 1983). Subsequently cognitive behavioural practice has developed as the main approach in pain management and has been widely used and evaluated since the 1980s. The International Association for the Study of Pain (IASP) has emphasized the need for multidisciplinary management of patients with chronic pain and for attention to the physical, psychological, social, vocational, recreational, and other functional aspects of persons with pain-related disability (Loeser JD, et al. 1990). Accordingly, physiotherapy with its ability to provide treatment for local spinal problems and their secondary functional changes, reorganize altered physiological patterns and improve the psychosocial state of the patient is acknowledged as part of the multidisciplinary management of pain (Bonica, 1990). This level overlaps and integrates with the fields of occupational therapy (training of work related tasks, psychotherapy (training of social competence) and physical training (improvement of physical performance).

Clinical guidelines for low back pain published in the New Zealand Journal of Physiotherapy (accrued from library databases at the University of South Australia and various Internet search engines), reviewed nine eligible guidelines differing in their strength of evidence, diagnostic criteria, interventions and measures of outcome providing guideline features: clinical decision-making systems, clinical care recommendations, best practice management strategies (patient handouts) and clinical indicators for quality improvement. These guidelines advocated patient-centred outcomes and assumed that practitioners had access to the information and applied the recommendations effectively (Grimmer K et al. 2002).

It is suggested that recommendations for future guidelines would benefit from recent information and studies collated by the IASP on rehabilitation and physical therapy modalities that have been identified as beneficial to patients with chronic pain.

The recommended physiotherapy guidelines for the management of chronic low back pain are:

- Recognition of a broad biopsychosocial model of health (and illness) and the positive role of activity in health and healing, emphasis on function, rather than impairment, and reliance upon clinical evidence has transformed physiotherapists’ practice. Therefore the development of a patient-centred rehabilitative approach has emerged that emphasizes the restoration of normal movement and function which incorporates physiotherapy as a vital component of the collaborative approach required for effective pain management (Harding, Simmonds and Watson, 1998).

Pain rehabilitation is a useful and cost-effective approach to chronic pain management. The pain rehabilitation model below makes patient’s responsible partners in their own progress, enlists the support and assistance of other providers and places all aspects of treatment into a clear and goal-oriented context (Vasudevan SV, 2004).

### Principles of rehabilitation

Rehabilitation is an important component of chronic pain management and should employ a skilled team to:

- **Restore function**
- **Alleviate pain whenever possible**
- **Improve pain management skills for the patient with persistent pain**

Chronic pain rehabilitation may be considered an active treatment as opposed to maintenance

- **Active:** the patient and the team work directly to improve function and reduce pain within a set time frame. Treatment is designed to ‘cure’ or ‘alleviate’ the underlying condition, while improving function.
- **Maintenance:** focuses on self-management (e.g., exercise, cognitive-behavioural) and ongoing symptomatic medical intervention.

**Suggested Guidelines:**

**Physiotherapy Management of Chronic Low Back Pain:**

**Non-pharmacological management**

Phyllis Berger BSc Physio (Wits)
Patient must be motivated to, and capable of, participating. Conditions requiring urgent surgical or medical interventions (e.g. neurological emergency, infection) must be ruled out.

Implementation

1. Comprehensive assessment: A thorough history and examination leads to clear diagnosis and a structured treatment plan. Treatment must be aligned to presentation of symptoms and the condition.

“Pain is a subjective phenomenon: believe the patient – elic it the meaning of pain to the patient. Assess the pain carefully and reassess regularly: as pain cannot be objectively measured, quantify severity and characterize etiology by the patient’s description of the pain; include interference with sleep and daily activities; make a diagnosis as specific as possible. Respond to specific treatments and make pain visible to the patient by the use of the visual analogue scale 0 – 10 scale with 0 = no pain, 10 = worst imaginable. (Notes from Guidelines for Assessing and Treating Pain from: Massachusetts General Hospital Cares About Pain Relief Programme Project Director TE Quinn 2002)".

“Physiotherapy clinical assessment has traditionally relied on clinical tests of impairment but these tests correlate poorly with patients’ pain and dysfunction. These tests of muscle strength and range of motion in isolation lack sensitivity, specificity and responsiveness. The best performance testing is quick, simple and meaningful to both the patient and practitioner. Patients with pain tend to move more slowly than pain-free persons, generate less force during muscle testing and may have poor endurance during exercise. The physical performance battery (PPB) measures time taken and distance reached or walked during a set of tasks. The PPB was developed for use with persons with low back pain and it has demonstrated good intra- and inter-rater reliability and stability over time and differentiates patients from pain-free controls. The assessment battery of Harding et al. for use in a diverse chronic pain population detects change following pain management (Notes from Pain Clinical Updates Harding et al.1994).”

2. Treatment: Multiple concurrent interventions designed to address all issues

3. Physical and occupational therapy

4. Explanation and education of the patient on chronic back pain

5. Exercise – most common treatment method, likely most effective.

Different specific exercise programmes are appropriate for patients with different pain conditions. They include:

- Postural training and stabilisation
- Stretching
- Strengthening
- Home exercise programme tailored to the individual – this is vital
- Aerobic conditioning

6. Work conditioning/ work hardening/activities of daily living (ADL)

7. Ergonomic modifications

8. “Take advantage of the patient’s ability to learn and use their own internal resources.

Involve the patient in creating and assessing the plan of care; teach the patient about pain and the many ways it can be treated; teach the patient about self-care strategies such as self-hypnosis, meditation, distraction and bio-behavioural techniques (Quinn TE, 2002)“.

9. Modalities used in conjunction with active exercises (thermal, massage, electrical stimulation, traction, Transcutaneous electrical nerve stimulation (Tens), myofascial release, dry needling, mobilization (Geisser ME et al. 2005), acupuncture (Thomas et al. 2006) where appropriate) – many patients achieve transient relief and these approaches should be used sparingly in these particular individuals although many patients do attain lasting or complete relief.

Despite the long history of the availability and use of physical rehabilitation approaches, traditional medicine in western societies has generally de-emphasized physical approaches and has focused on pharmacologic and surgical interventions for pain problems. However many Third World countries, have relied on physical approaches for the management of pain problems because they are easily available, inexpensive, noninvasive, associated with less morbidity and foster independent functioning (Vasudevan SV 1996). Modern physical approaches that have proved successful through evidence based science can assist and make a valuable contribution to advancing concepts in pain medicine.

Recent advances in neurophysiology and modulation of pain and its perception provide a clearer rationale for the use of physical agents for rehabilitation of patients with pain and related disability (King et al. 1992).

Electrical pain modulation occurs through sensory neuro-modulation of peripheral and central nerve impulses. The rationale is based on the concept of a gating mechanism in the dorsal horn of the spinal cord where small diameter, unmyelinated C and thinly myelinated A delta fibre activity can be modulated (suppressed) by the larger diameter myelinated A beta fibre activity, thus reducing pain. Studies have identified endogenously produced opioid-like substances that are produced by these different frequencies of Tens such as enkephalin and endorphin which have potent opioid agonist activity. High frequency (150 – 200Hz), low intensity Tens stimulation involves the spinal segmental inhibitory GABAergic interneuron in the spinal cord and activates delta opioid receptors in the spinal cord and rostroventral medulla. Stuka, Hoeger and Skyba, 2002 found that higher frequencies and longer periods of application (at least 40 mins) were more effective in achieving pain relief than previously thought and less likely to produce tolerance. Low frequency (1-4Hz), high intensity Tens affects the opioid pathways through the mu opioid receptors and these affect central mechanisms at both spinal cord and brainstem sites that exert mainly inhibitory effects (Ainsworth L et al. 2006). Other studies have demonstrated that low frequency (King et al 2005) also activates peripherally located alpha-2A adrenergic receptors which may impact on sympathetically mediated pain.

Other changes in tissue also affect pain relief such as decreasing inflammation, oedema, improving circulation
and in mobility and strength. The rationale for these concepts is due to the fact that biological systems are known to be greatly affected by electrical treatment (Cheng, et al. 1982\(^2\)). Different types of current have different effects on the body particularly: modulated direct current (APS with pulses of 0-150Hz, 0.8 – 6.6ms sharp, rectangular spike wave with an exponential decay, continuous, mono-phasic, non-symmetrical) that reduces inflammation and oedema, improves circulation and affects peripheral temperature changes, interrupted direct or surged currents that produce functional (motor nerve) electrical stimulation that impacts upon strength and mobility, microcurrents (Alpha-stim, 0.5-1Hz, alternating, uneven square-waves) that are mostly subliminal that produce endorphins and affect wound healing, hyperaesthesia, inflammation and aberrant nerve conditioning and cranial microcurrent (Alpha-stim, 0.5-1Hz) that increases endorphins, improves aberrant nerve conditioning and induces relaxation.

“Use of non-pharmacologic approaches should be used to complement, not replace, appropriate analgesic therapy (Quinn TE, 2002\(^3\))”.

An ALGORITHM has been suggested below that may assist in deciding best treatment practice when using electrical modulation for pain relief and healing. The principle of the algorithm assumes that Tens, when used for three days continuously for eight hours per day at home may in at least 10% of patients provide complete relief of pain and restore full mobility and others may improve pain by at least 60% while 20% may have no response (Berger P 1999\(^2\)). If the desired response is achieved then the patient may move towards complete rehabilitation but if this is not achievable other modalities are applied that may bring the patient into better alignment with pain relief. Patients who are treated with a combination of physical treatment in the clinic should experience TENS for at least 40 mins to achieve optimal results.

Patients who experience hyperaesthesia and or allodynia may best be suited with subliminal microcurrent therapy, acupuncture and cranial electrotherapy (CES) to activate central mechanisms to increase endorphins and induce relaxation. Other techniques such as breathing exercises, visualization and self-hypnosis also activate the descending mechanisms to increase endorphins. Explanation, information, advice on pain and its treatment and reducing fear are also important factors in supporting these descending mechanisms.

Functional electrical stimulation (FES) is an important part of re-establishing a connection from the periphery to the brain. The motor cortex often receives misinformation from the periphery due to injury and disuse in chronic pain situations and FES strengthens weakened muscle fibres, assists with improved function, mobilizes joints and improves co-ordination. Using mirrors to improve mobility helps as the disused limb is hidden from view by a mirror and the patient observes the normal limb or region of the body moving in the mirror and this appears to be the affected side and this provides a fake/unreal visual of information that provides a new connection to the motor cortex from the disused limb.

A model of advancement toward rehabilitation supported by the IASP in Clinical Updates on Physical Therapy for Chronic Pain provides the following input (Harding VR et al, 1998\(^4\)):

Planning and pacing assists the patient with a balance between exercise and support. It encourages rest for the injured area and prevention of re-injury through use of orthotic devices (braces, corsets, splints).

Activity, activity related goal setting, and pacing play key roles in the rehabilitation of patients with chronic pain. Pacing and goal setting even out the activity peaks and troughs controlled by pain so as to achieve a moderate activity-rest cycle. Gradual controlled increases in general activity level will avert triggering sudden increases of pain that lead to reduction of activity. Activities are paced by timing and/or the introduction of exercise quotas interspersed with periods of rest or a different activity. Establishing specific, challenging but attainable goals can actually facilitate task performance and results from meeting expectations of efficacy and outcome. Belief that a specific outcome can be achieved by a specific behaviour may be the most potent determinants of change during rehabilitation. Increased self-efficacy is closely linked to successful rehabilitation as a positive outcome that is defined as increased activity, improved coping and reduced pain behaviour. Confidence is often low when tackling new goals or returning to previously abandoned activities. To increase confidence, patients need to attempt something previously feared, achieve it, and recognize it as their own achievement. Persistent goal attainment will re-enforce self-efficacy and lead to the perception of mastery over the problem or task. Goal setting should be a matter of negotiation between the patient and the therapist.

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**DIAGRAM**

Algorithm for the use of electrical and physical modalities in chronic back pain

[Diagram showing the algorithm with various treatment options and responses.]

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**Notes:**

1. Different types of electrical currents have different effects on the body. Modulated direct current (APS) can reduce inflammation and oedema, improve circulation, and affect peripheral temperature changes.
2. Microcurrents can increase endorphins and affect wound healing.
3. Cranial microcurrents can improve aberrant nerve conditioning.
4. Functional electrical stimulation (FES) can strengthen weakened muscle fibres and assist with improved function.
5. Mirrors can help improve mobility by providing a visual of the normal limb in the mirror.
6. Planning and pacing can help balance exercise and support, encouraging rest for the injured area and preventing re-injury.
7. Activity, goal setting, and pacing are important for reducing pain and improving quality of life.
8. Self-efficacy is crucial for successful rehabilitation and should be encouraged through goal setting and sustained achievement.
9. Persistent goal attainment is necessary for re-enforcing self-efficacy and recognizing mastery over the problem or task.
apt and should always be personally relevant, interesting, measurable and achievable to the patient, both functionally and socially.

Exercise regimens should be regular and gradually increase in duration and intensity. Adherence is greatest with exercises that are easily incorporated into a patient’s routine and the patient is more likely to participate in exercises/activities that are interesting and if others are involved. Good information about exercise/classes to assist patients in making choices, overcoming unhelpful beliefs and modifying behaviour (increasing activity and exercise) is advocated.

Inevitably, patients may experience exacerbation of the pain problem at some time which should never be seen as a failure or of patients’ inability to manage the condition. Identification of a physical event and or cumulative psychological stresses that caused the relapse can be helped by the physiotherapist who will suggest strategies to cope with the situation such as visiting health professionals, use of pain medication, physical modalities that ease pain, brief rest or relaxation and then a rapid plan for resumption of activities. Plans to resume activities are critical as it provides an action plan in readiness for exacerbations that can help the patient retain a sense of control. Rehabilitation for chronic pain suffers is a life less dominated by pain and can be long and complex and involves overcoming physical and psychological obstacles. The physiotherapist helps patients: address obstacles to rehabilitation, use information accurately, provide helpful feedback and reinforcement to guide efforts towards a return to activities and achievement of valued personal goals.

References
6. Fordyce WE. Behavioural Methods for Chronic Pain and Illness 1976 CV Mosby, St Louis, MO.
Psychological Interventions for Acute and Chronic Pain in Children

Inadequate prevention and relief of children's pain are still widespread

Over the last two decades, research into the nature, assessment, and treatment of children's pain has grown exponentially. It is now generally accepted that infants and children can feel pain. Pain assessment instruments with good psychometric properties are available for use in infants, toddlers, and children, including those with communication deficits and other impairments. Numerous drug and non-drug interventions have been developed and tested in a variety of clinical populations and settings. However, inadequate prevention and relief of children's pain are still widespread, a deficiency highlighted during the current IASP Global Year Against Pain in Children. This issue of Pain: Clinical Updates focuses on psychological treatment of acute and chronic pain in children, placing special emphasis upon interventions for which a credible evidence base exists. In this article, the word "children" refers to all individuals in the pediatric age range from neonates through adolescents.

Physical and psychological responses to pain not only affect children's health directly, but also may predispose them to develop chronic pain in adulthood

Pediatric Pain

All children normally experience pain from sources such as minor bumps, cuts, bruises, occasional headaches, toothaches, "growing pains," fractures, and dental procedures. Pain may also result from a chronic medical condition that involves diagnostic and therapeutic procedures such as lumbar puncture, bone marrow aspiration, or venipuncture. Pain has significant adverse emotional and social consequences for children and their families. Physical and psychological responses to pain not only affect children's health directly, but also may predispose them to develop chronic pain in adulthood.2,3

Pain perception in children reflects the complex, moment-to-moment integration of affective, behavioral, cognitive, and physiological components.
within a developmental trajectory and a sociocultural context. Thus, pain management may be optimized when all components of the child’s pain experience are evaluated and addressed. A variety of psychological interventions are described in the research and clinical literatures, including distraction, play therapy, psycho-educational approaches, hypnosis, biofeedback, and guided imagery. The very number of available interventions may be a source of confusion as to which one is best for which child and setting. Selecting the most appropriate treatment not only is proper clinical practice, but also is necessary for cost-effective, evidence-based care.

It is important to replicate positive preliminary findings with independent trials

Evidence-Based Psychological Interventions

A decade ago, the American Psychological Association (APA) Task Force on Promotion and Dissemination of Psychological Procedures recommended that clinical guidelines for treatment interventions be evaluated with respect to how closely they adhere to empirical evidence on treatment outcomes. In pediatric pain management, psychological treatment is defined as a verbal interaction between a health care professional and a child that leads to changes—from a less adaptive state to a more adaptive state—in the child’s pain-related thoughts, feelings, and behaviors. Chambless and Hollon proposed an approach to determine when a psychological treatment for a specific problem or disorder may be considered to be efficacious. They assigned the greatest weight to randomized controlled clinical trials or their “N of 1” (single case) equivalent. Such trials of treatment efficacy should be followed by research on effectiveness, i.e., the benefit of applying the treatment in real-world clinical practice including diverse patient populations, as well as by cost-effectiveness research. Chambless and Hollon emphasized the importance of performing independent trials to replicate positive preliminary findings. They described several factors that should be weighed in evaluating whether studies supporting a psychological treatment’s efficacy are sound, including the existence of a standardized treatment manual, the training and supervision of therapists, and appropriate statistical analyses. Empirically supported treatments were defined as clearly specified psychological treatments shown to be efficacious in controlled research with a delineated population. In turn, a treatment must show efficacy in at least two randomized controlled trials by independent research teams before it can be labeled efficacious. If only a single study supports a treatment’s efficacy, or if all of the research has been conducted by one team, the findings are considered promising, and the treatments are considered possibly efficacious, pending replication.

Acute Pain Management

In 1998, when the World Health Organization developed and published guidelines for the management of pain in children with cancer for medical procedures, in all cases the use of a combination of a psychological with a pharmacological approach was supported, and aggressive, preemptive approaches were emphasized. A substantial number of psychological interventions for procedural pain management are in clinical use. These interventions include psychoeducational approaches, deep breathing, distraction, relaxation, play therapy, guided imagery, cognitive therapy, hypnosis, filmed modeling, behavioral rehearsal, and operant techniques that include reinforcement schedules. However, only two interventions—cognitive therapy and hypnosis—qualify as empirically validated and efficacious according to the APA framework described above.

Only two interventions—cognitive therapy and hypnosis—qualify as empirically validated and efficacious according to the APA framework

In terms of postoperative pain management, the need for interventions that reduce children’s pain is growing as a result of the continued demand for outpatient surgery, shortened hospital stays, and difficulties with pain management in terms of insufficient resources and drug side effects, both in the ambulatory setting and at home. A recent randomized controlled trial by Huth et al. investigated imagery administered pre- and postoperatively, as a supplement to routine analgesics, for reduction of pain and anxiety after tonsillectomy and adenoidectomy in the ambulatory setting and at home in 73 children aged 7–12 years. After controlling for trait anxiety (i.e. personality-related anxiety) and for opioid and non-opioid analgesic intake 1–4 hours before pain measurement, the investigators found significantly lower self-reported pain and situation-related anxiety 1–4 hours after surgery (but not 22–27 hours after surgery) in the imagery group.

Children enjoy applying psychological interventions, obtaining relief without destructive or unpleasant effects

In addition to their intrinsic usefulness in symptom management, psychological techniques are safe, have not been observed to produce adverse effects, and avert drug-drug interactions seen with supplemental pharmacotherapy. Children enjoy the interventions, obtaining relief without destructive or unpleasant effects. There is no reduction of normal function or mental capacity and no development of tolerance to their beneficial effect. Indeed, psychological techniques may be
The goal of psychological interventions is to shift the child from a helpless state to a more adaptive state of empowerment and control.

**Chronic Pain Management**

Recent narrative reports and systematic reviews and meta-analyses suggest that multicomponent cognitive-behavioral therapy (CBT) is effective in the management of chronic pain of young patients, particularly in the treatment of headaches. CBT is a form of psychotherapy that involves recognizing unhelpful or destructive patterns of thinking (with their corresponding ways of feeling and behaving), then modifying or replacing these with more realistic or adaptive ones. Eccleston et al. conducted a systematic review and subset meta-analysis of published randomized controlled trials of psychological therapies for children with chronic pain. Eighteen studies, six conducted in community (school) settings, met criteria for inclusion in the review. Meta-analysis was possible for 12 headache trials and 1 trial of recurrent abdominal pain. For these trials, the odds ratio for a 50% reduction in pain was 9.62, and the number needed to treat was 2.32, indicating that the psychological treatments examined were efficacious in reducing the pain of headache. The authors found that psychological treatments, particularly relaxation and CBT, were highly effective in reducing the severity and frequency of chronic pain, including headaches, in children.

**Suggestions for Further Research**

Research on CBT and other psychological interventions such as hypnosis for pain management has significant promise to expand upon and refine current practice. A review of the pediatric pain management literature highlights the importance of creating and delivering interventions that match specific patient characteristics and needs. Several variables, including age, gender, developmental level, and previous pain experience, are critical design components in individualized treatment plans. This information can help clinicians as they design highly focused, often brief, interventions that match the needs of each child and family.

Because of its proven efficacy, CBT will most likely continue to be offered in conjunction with pharmacological interventions. Therefore, further research examining combinations of pharmacological interventions with CBT is needed. Investigators must identify which individual components of complex CBT protocols are most effective and determine the best combinations of these components with specific pharmacological agents. Research on the effect of therapist-administered versus self-administered treatments is also necessary. If children and their parents can successfully implement CBT interventions on their own after suitable training, the cost of these interventions would be less than if they were provided by a clinician.

**Innovations in pediatric pain management need not be “high-tech”**

**Conclusion**

Psychological interventions for pediatric pain control are increasingly applied in hospitals in most Western countries. However, their availability remains sparse and inconsistent. Pediatric pain is a health care issue that results in significant suffering and financial cost, so we must synthesize the scientific evidence to identify those psychological interventions whose widespread and consistent use is justified. Although controlled clinical studies on psychological analgesia have substantial room for improvement, the available evidence indicates that both CBT and hypnosis are useful in acute and chronic pain. Innovations in pediatric pain management need not be “high-tech.” In most cases, excellent analgesic results can be achieved through application of standard pharmacological and psychological approaches, continuous patient assessment, and patient and family participation in planning and implementing treatment. The time has come for us to give priority to bridging the gaps between theoretical developments, evidence derived from clinical research, and current clinical practice in pediatric pain management.
References


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Pain affects spouses too: Personal experience with pain and catastrophizing as correlates of spouse distress

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Abstract

Chronic pain has adverse effects on individuals with chronic pain (ICPs) as well as their family members. Borrowing from an empathy model described by Goubert et al. (2005), we examined top-down and bottom-up factors that may be related to psychological well-being in the spouses of ICPs. A diverse community sample of 113 middle-aged spouses of individuals with chronic pain (ICPs) completed measures on pain severity and spouse pain catastrophizing (PCS-S; Cano et al., 2005). Results showed that almost half (48.7%) of spouses reported chronic pain themselves and that pain in the spouse accounted for within-couple differences on psychological distress. That is, in couples where only the ICP reported pain, ICP psychological distress was greater than their spouses. However, when both partners reported chronic pain, there was no significant difference in psychological distress between partners. Hierarchical regression analyses showed that spouse magnification catastrophizing was associated with depressive and anxiety symptoms, and that helplessness catastrophizing was associated with depressive symptoms for spouses of ICPs who also reported chronic pain but not for spouses of ICPs without chronic pain. The results are discussed in light of interpersonal processes that may affect spouses’ distress.

Keywords: Chronic pain; Couples; Depression; Anxiety; Catastrophizing; Spouses

1. Introduction

Pain has an adverse impact on the significant others of individuals with chronic pain (ICPs). For example, spouses of ICPs report elevated psychological distress when compared to spouses of diabetic patients and healthy individuals (Shanfield et al., 1979; Rowat and Knall, 1985; Flor et al., 1987a; Subramanian, 1991; Smith et al., 1999; Bigatti and Cronan, 2002). An understanding of how pain impacts the psychological distress of spouses requires a conceptual framework that accounts for characteristics of both partners. One such framework, developed by Goubert et al. (2005), suggests that both top-down (i.e., observer characteristics) and bottom-up influences (i.e., ICP pain cues) provide pain observers (e.g., spouses of ICPs) with knowledge about ICPs’ experiences. This knowledge then contributes to a variety of spouse affective responses including psychological distress. The purpose of this study is to examine how top-down and bottom-up characteristics directly relate to psychological distress in spouses of ICPs.
variables might impact spouse distress because they provide the observer spouse with information and knowledge about the ICP's pain. While the literature has focused on pain catastrophizing as a correlate of psychological distress in ICPs (Keefe et al., 1989; Sullivan and D'Eon, 1990; Geisser et al., 1994; Turner et al., 2000, 2002), research also demonstrates that spouses catastrophize about ICPs' pain (Cano et al., 2005). As a top-down influence, spouse pain catastrophizing contributes to spouses' sense of knowing about the ICPs' pain. Therefore, spouse pain catastrophizing may create a sense of exaggerated or heightened concern about ICPs' pain that contributes to spouse psychological distress.

As indicated earlier, spouses' own personal experiences with pain may also be considered a top-down variable. Although personal experience with pain appears to affect accuracy of pain judgments (Robinson and Wise, 2004), no published studies of which we are aware have examined the association between spouses' personal experiences of pain with their own elevated psychological distress. Chronic pain in the spouse may intensify the negative impact of catastrophizing because the knowledge about ICP pain is enhanced with first-hand experience.

Finally, bottom-up variables such as ICP pain severity provide additional information and cues about the ICP that may heighten distress in spouses. Previous studies have demonstrated the importance of pain severity in spouse distress (Schwartz et al., 1991); however, no studies to date have examined the top-down and bottom-up influences simultaneously. As the model suggests, these influences may contribute uniquely and jointly to spouse distress.

In sum, we expected that spouses' psychological distress would be a function of these top-down and bottom-up influences. Specifically, we expected that spouses' pain catastrophizing and personal experiences with chronic pain as well as ICP pain severity would be related to spouses' psychological distress. Such findings would support the validity of models accounting for characteristics of observers and ICPs, and suggest that spouse distress is deserving of research and clinical attention.

2. Method

2.1. Participants

The participants were 139 married couples, which included one couple member who had a chronic musculoskeletal pain condition (ICP) and his/her spouse. A subset of these participants participated in Cano (2004, 2005). The spouses of the ICPs were predominately male (58.4%, n = 66) and the sample was diverse (53.1% Caucasian, 38.9% African American, 8.0% other [Hispanic/Latino, Native American, Asian, multiracial]). On average, spouses were 54 years old (SD = 13.6), had 14.4 years of education (SD = 2.7), and had been married 20.6 years (SD = 16.7).

To clarify terminology, the current study consisted of ICPs and their spouses. The individual with the chronic musculoskeletal condition was deemed the “ICP” and their partner as the “spouse.” Throughout the rest of the paper, the term “spouses” is used to identify the spouses of ICPs as a group. A distinction was made between “healthy spouses” and “spouses with chronic pain (SCPs).” When both partners in a couple reported chronic pain, the couple member with the musculoskeletal pain condition (e.g., osteoarthritis) as opposed to other chronic pain conditions was chosen as the ICP. If, however, both partners reported a chronic musculoskeletal pain condition, the ICP was identified as the individual who had the most severe or debilitating pain as indicated by reports from each partner during the telephone screening interview. General pain information obtained from both partners revealed that ICPs had more severe pain on a 5-point Likert scale question on pain severity (M = 4.0, SE = .12) than SCPs (M = 3.32, SE = .13), t(68) = 4.02, p < .01, consistent with the study design.

Almost half of the spouses reported chronic pain themselves (48.7%, n = 55). The most common location for SCPs to have pain was in their lower back or knees (49.1%, n = 27 for both locations). Of the spouses who reported pain, 58.2% (n = 32) had received a diagnosis for their pain, the most common being osteoarthritis (41.6%, n = 22). See Table 1 for additional information on spouses who reported pain.

2.2. Measures

2.2.1. Psychological distress

The Mood and Anxiety Questionnaire (MASQ; Watson and Clark, 1991) provides five subscales to assess symptoms of anxiety, depression, and general distress. The MASQ has a stable factor structure in adult samples (Watson et al., 1995) and in community and clinic pain samples (Geisser et al., 2006). The non-specific depression subscale (12 items, a = .90) and the anhedonic depression subscale (22 items, a = .94) measure depressive symptoms whereas the non-specific anxiety (11 items a = .84) and anxious arousal (17 items, a = .85) assess anxiety symptoms. The inclusion of anxiety symptoms in the current study is important to note as this type of psychological distress has not yet been explored in spouses of ICPs in the current literature. Means for the non-specific depression scale, anhedonic depression scale, non-specific anxiety scale, and the anxious arousal scale were 22.2 (SD = 8.6), 57.2 (SD = 15.6), 19.7 (SD = 6.5), 27.3 (SD = 8.1) for patients and 20.3 (SD = 7.8), 51.3 (SD = 15.1), 17.0 (SD = 5.9), 23.9 (SD = 7.5) for spouses, respectively. These means were very similar to the means for community men and women reported by Watson et al. (1995). Spouses’ non-specific depressive symptoms and anhedonic depressive symptoms were highly correlated with one

| Table 1 Pain ratings and duration for spouses with chronic pain |
|-----------------|-----------------|
| Scale | Mean (SD) |
| Pain severity (scale from 1-5) | 3.3 (1.11) |
| Average visual analogue rating scale | 44.3 (28.8) |
| Average length of pain (in months) | 130.85 (113.21) |

Note. N = 55.
another \((r_{113} = .77, p < .001)\), as were non-specific anxiety and anxious arousal symptoms \((r_{113} = .77, p < .001)\). Therefore, a composite depressive and anxiety symptom score was calculated to protect against Type I error and redundant results in later analyses. The inter-item reliability \(r = .78\), as well as the pain \((34 \text{ items})\) and anxiety \((28 \text{ items})\) composite scores were excellent \((z = .95 \text{ and } .91, \text{ respectively})\).

Comparisons between SCPs and ICPs were conducted to further understand spouses’ psychological distress, particularly in light of the within couple differences that have been reported in the literature \(\text{(e.g., Ahern and Follick, 1985; Flor et al., 1987b; Flor et al., 1987a)}\). A repeated measures ANOVA was conducted separately for each composite score to determine if spouse pain status was an important correlate of within-couple differences. These analyses showed that the ICP-spouse differences in depressive symptoms were moderated by the pain status of the spouse \(t[1] = 7.72, p < .01\). Post hoc paired \(t\)-tests were conducted and revealed that within-couple differences in depressive symptoms were found only for couples in which only one partner suffered from chronic pain \((r_{111} = 4.53, p < .001; \text{ICP } M = 79.79, SE = 3.01 \text{ and spouse } M = 65.32, SE = 2.28, \text{ respectively})\). ICPs and SCPs did not report significantly different mean scores on symptoms of depression \((r_{111} = 0.69, p > .05; \text{ICP } M = 81.11, SE = 3.31 \text{ and SCP } M = 78.55, SE = 3.40, \text{ respectively})\). Similar results for symptoms of anxiety were found for both spouses who denied a pain condition \((r_{111} = 5.22, p < .001; \text{ICP } M = 44.81, SE = 1.50 \text{ and spouse } M = 35.49, SE = 0.94)\) and SCPs \((r_{111} = 1.15, p > .05; \text{ICP } M = 49.69, SE = 2.17 \text{ and SCP } M = 46.47, SE = 2.05)\). These differences suggest that spouses’ personal experiences of pain are an important top-down influence that should be examined as a correlate of spouse distress.

### 2.2.3 Pain catastrophizing

The Pain Catastrophizing Scale-Significant Other Version (PCS-S) \((\text{Cano et al., 2005})\) was adapted from Sullivan et al.’s \((1995)\) Pain Catastrophizing Scale (PCS) for use with significant others by rewording the questions so that spouses indicated the degree of their catastrophicizing about ICPs’ pain. The PCS-S consists of 13 items and assesses three components of catastrophizing: magnification \((3 \text{ items}; \text{e.g., } \text{"I wonder whether something serious may happen")}, \text{helplessness (6 items;} \text{e.g., } \text{"There is nothing I can do to reduce the intensity of the pain")} \text{, and rumination (4 items; e.g., } \text{"I keep thinking about how much it hurts")}. The PCS-S has a stable factor structure that is invariant across gender and racial groups \((\text{Cano et al., 2005})\). In the current study, each of the three components of catastrophizing was analyzed individually. This is particularly important as there are no studies of which we are aware that explore each dimension separately as a correlate of marital distress. Inter-item reliabilities for the PCS-S subscales in the current sample were acceptable \((\text{magnification } z = .77, \text{helplessness } z = .78, \text{ and rumination } z = .84)\). There were no differences between SCPs and healthy spouses on dimensions of pain catastrophizing \((p > .05)\).

### 2.2.4 Marital satisfaction

The Dyadic Adjustment Scale (DAS) \((\text{Spanier, 1976})\) measures overall marital satisfaction and discord. The DAS consists of 32 items that measure agreement on a variety of topics \(\text{(e.g., finances and world views), degree of affection, and general marital happiness. The range of the scale is from 0 to 151 with higher scores indicating greater marital satisfaction. Marital satisfaction was included as a covariate in the hierarchical regression analyses because marital satisfaction is consistently related to depressive symptoms in pain samples} (\text{see Leonard et al., 2006})\) and marital satisfaction is important aspect of the spouse’s experience of pain \((\text{Maruta et al., 1981; Ahern and Follick, 1985; Flor et al., 1987a; Geisser et al., 2005})\). The alpha for the spouses was .93, indicating excellent inter-item reliability. Scores on the DAS were not significantly different for SCPs and healthy spouses \((p > .05)\).

### 2.3 Procedure

Couples were recruited from newspaper advertisements as part of a larger study of marriage and chronic pain. Upon responding to these advertisements, participants were screened over the telephone to ensure eligibility prior to the completion of any study related materials. Couples were eligible if they met all of the following criteria: \((1)\) married or living together for a minimum of two years, \((2)\) at least one spouse experienced a chronic musculoskeletal pain condition, \((3)\) the pain condition lasted at least six months, \((4)\) neither couple member had been diagnosed with a terminal illness, \((5)\) both couple members were able to demonstrate adequate cognitive ability as assessed by a telephone version of the Mini-Mental Status Exam (MMSE) \((\text{Folstein et al., 1975})\). Once a couple was deemed eligible, an appointment was made for the couple to come to the laboratory where research assistants described the protocol to the couples and obtained written consent. Each partner then completed questionnaires independently and participated in the larger study protocol. Upon completion of the study, participants were debriefed and compensated $100 for their effort.

### 2.4 Analysis plan

Of the 139 couples recruited, 25 of the spouses who initially participated did not complete the PCS-S and consequently were excluded from analyses. Additionally, two individuals...
did not provide complete data for the MASQ and were excluded. There were no significant differences on pain catastrophizing, ICP pain severity, or their own likelihood of reporting pain ($p > .05$) between participants who did and did not complete the questionnaires. There was a significant difference, however, on marital satisfaction ($t[137] = -2.60, p < .05$), where spouses who provided complete data had higher mean scores on the DAS ($M = 111.59, SE = 1.67$) than those who did not ($M = 102.13, SE = 4.26$). The final sample consisted of 113 spouses when non-completers were excluded from the analyses.

Pearson product–moment correlations were conducted to examine the bivariate relationships of the top-down variable of pain catastrophizing, bottom-up variable of ICP pain severity, and potential covariate of marital satisfaction with depressive and anxiety symptoms. We also examined the extent to which the top-down variable of personal experiences with pain would be related to spouse distress through $t$-tests.

Next, hierarchical regressions were conducted to examine the overall relationship between pain in the spouse and catastrophizing to spouses’ depressive and anxiety symptoms as well as any interactions. Each of the catastrophizing subscales was tested separately. Before completing the regression analyses, however, all variables were centered as recommended by Cohen (1988) and Holmbeck (2002) to reduce multicollinearity among the variables. Each of the regressions included marital satisfaction and gender as covariates entered in the first step. Marital satisfaction was included in light of the significant correlation between marital satisfaction with spouse depressive ($r = -.42, p < .001$) and anxiety symptoms ($r = -.28, p < .01$), as well as the consistent relationship between marital satisfaction and psychological distress in the existing literature (e.g., Kerns and Turk, 1984; Kerns et al., 1990; Cano et al., 2000, 2004). Gender was also included as a covariate because analyses revealed significant gender differences on depressive symptoms ($t[112] = -2.44, p < .05$), with female spouses reporting more symptoms of depression than their male counterparts ($M = 78.36 \pm 3.68$ and $M = 67.65 \pm 2.39$, respectively). The gender difference for symptoms of anxiety was in the same direction and approached significance ($t[112] = -1.86, p < .05$). Therefore, gender was included as a covariate in analyses predicting depressive and anxiety symptoms. The second step for the regression of depressive symptoms included the main effects for one of the catastrophizing subscales, pain in the spouse, and ICP pain severity, while for anxiety symptoms ICP pain severity was excluded as it was not significantly correlated with symptoms of anxiety ($r = .12, p > .05$). The third step of the regressions included the two-way interaction terms between the variables entered in step 2. The depressive symptom regression included a fourth step consisting of a three-way interaction between ICP pain severity, pain catastrophizing, and pain in the spouse. There were six regressions calculated in total: one for each subscale of the catastrophizing measure (magnification, helplessness, and rumination) predicting either depressive or anxiety symptoms. Any significant interactions in the regressions were then subjected to post hoc analysis as per Holmbeck (2002), where multiple regression analysis is used to estimate the expected value of the dependent variable at high (+1SD) and low (−1SD) levels of the independent variable.

3. Results

3.1. Correlations and $t$-tests

Bivariate correlations are shown in Table 2. As one would expect, depressive and anxiety symptoms were strongly related to each other and the three pain catastrophizing subscales were also significantly related to each other. As hypothesized, the bottom-up influence of ICP pain severity was significantly and positively related to spouses’ depressive symptoms. ICP pain severity was also related to each of the three catastrophizing subscales. The top-down factors of magnification and helplessness catastrophizing were also correlated significantly with depressive symptoms, with moderate effect sizes. However, rumination was not significantly related to either depressive or anxiety symptoms. In addition, magnification and helplessness were not significantly related to anxiety symptoms. The potential covariate of marital satisfaction was significantly and negatively related to depressive symptoms and magnification and helplessness catastrophizing.

Independent samples $t$-tests were conducted to examine the association between the top-down variable of

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Correlations among catastrophizing subscales, pain severity, and psychological distress</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Depressive symptoms</td>
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<tr>
<td>Depressive symptoms</td>
<td>--</td>
</tr>
<tr>
<td>Anxiety symptoms</td>
<td>--</td>
</tr>
<tr>
<td>ICP pain severity</td>
<td>--</td>
</tr>
<tr>
<td>Marital satisfaction</td>
<td>--</td>
</tr>
<tr>
<td>Magnification</td>
<td>--</td>
</tr>
<tr>
<td>Helplessness</td>
<td>--</td>
</tr>
</tbody>
</table>

Note: (n = 113).

* $p < .05$.

** $p < .01$.
Pain relief from pain relief.

• Indicated for the treatment of mild to moderate post-operative pain.
• Fast onset of action – pain relief as early as 5 minutes*.
• Analgesic effect comparable to morphine 10 mg IM and ketorolac 30 mg IV**.
• Proven opioid-sparing effect***.
• Recognised safety profile of paracetamol.
• Ready to use in patients with an IV line.

**IV paracetamol 1 g (Perfalgan®) is therapeutically equivalent to IV paracetamol 2 g.

Release the true potential of paracetamol.
personal experience with chronic pain and symptoms of depression and anxiety. Results showed significant differences between SCPs and healthy spouses on reports of depressive symptoms ($t_{[112]} = -3.07, p < .01$) and anxiety symptoms ($t_{[112]} = -4.75, p < .001$). SCPs reported more depressive symptoms ($M = 78.55$ [SE = 3.40]) than spouses without pain ($M = 66.00$ [SE = 2.35]). Likewise, SCPs reported more anxiety symptoms ($M = 46.47$ [SE = 2.05]) than spouses without pain ($M = 35.83$ [SE = .98]).

### 3.2. Hierarchical regressions

Hierarchical regressions were conducted for both symptoms of depression and anxiety to determine the extent to which top-down and bottom-up variables are associated with psychological distress in spouses. Of particular interest were the interactions since earlier analyses demonstrated the bivariate relationships between variables.

For depressive symptoms, the interaction between spouses’ personal experiences with chronic pain and helplessness catastrophizing was significant (see Table 3). Post hoc examination showed that helplessness was positively related to depressive symptoms in SCPs ($\beta = .55, t = 4.17, p < .001$); however, helplessness was not significant in predicting symptoms of depression in spouses without chronic pain ($\beta = .12, t = 1.10, p = .27$) (see Fig. 1). Likewise, there was a significant interaction between magnification catastrophizing and the presence of chronic pain in the spouse, superceding the interpretation of the significant main effects of these variables (see Table 4). Post hoc examination showed that magnification was positively correlated with depressive symptoms for SCPs ($\beta = .52, t = 3.73, p < .001$); however, magnification was not significant in predicting depression in spouses without pain ($\beta = .08, t = .75, p = .46$). This interaction produced a similar pattern to that of helplessness and pain in the spouse, subsequently only one figure is displayed. All other interactions were not significant in these two regression analyses. Results from the regression with rumination showed main effects for gender ($\beta = .25, t = 3.09, p < .01$), marital satisfaction ($\beta = -.33, t = -4.00, p < .001$), and personal experience with chronic pain in the spouse ($\beta = .31, t = 3.79, p < .001$), however there were no significant interactions between these variables in relating to depressive symptoms.

Similar regressions were conducted for anxiety symptoms. As for depressive symptoms, the interaction between magnification catastrophizing and chronic pain

### Table 3

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE B</th>
<th>$\beta$</th>
<th>t</th>
<th>$R^2$</th>
<th>$\Delta R^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1 Gender of spouse</td>
<td>8.72</td>
<td>3.63</td>
<td>.19</td>
<td>2.41</td>
<td>.47</td>
<td></td>
</tr>
<tr>
<td>Marital satisfaction</td>
<td>-39</td>
<td>.11</td>
<td>-.31</td>
<td>-3.73</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 2 Helplessness</td>
<td>-1.11</td>
<td>.63</td>
<td>-.02</td>
<td>-1.7</td>
<td>.58</td>
<td>.11***</td>
</tr>
<tr>
<td>Spouse pain</td>
<td>11.69</td>
<td>3.72</td>
<td>.26</td>
<td>3.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICP pain severity</td>
<td>.50</td>
<td>.43</td>
<td>.14</td>
<td>1.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 3 Helplessness $\times$ spouse pain</td>
<td>2.01</td>
<td>.88</td>
<td>.26</td>
<td>2.27</td>
<td>.62</td>
<td>.04*</td>
</tr>
<tr>
<td>ICP pain severity $\times$ spouse pain</td>
<td>.13</td>
<td>.62</td>
<td>.03</td>
<td>.22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICP pain severity $\times$ helplessness</td>
<td>.04</td>
<td>.08</td>
<td>.05</td>
<td>.48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 4 ICP pain severity $\times$ spouse pain $\times$ helplessness</td>
<td>.17</td>
<td>.13</td>
<td>.15</td>
<td>1.31</td>
<td>.62</td>
<td>.00</td>
</tr>
</tbody>
</table>

Note: ICP, individual with chronic pain.

$p < .05$  
$p < .001$  

---

**Fig. 1. Interaction of helplessness and spouses’ personal experiences with chronic pain on depressive symptoms.**
in the spouse was significant (see Table 5). A similar pattern to depressive symptoms was noted as post hoc examination results showed magnification was a significant predictor of anxiety symptoms for spouses in pain ($\beta = .44, t = 3.24, p < .01$); however, catastrophizing was not significant in predicting anxiety in spouses without pain ($\beta = .05, t = .46, p = .65$). Because this pattern of association was similar to the depressive symptom results above, we do not present a separate figure for anxiety symptoms. Regression analyses for helplessness and rumination catastrophizing showed main effects for gender ($\beta = .17, t = 2.04, p < .05$ and $\beta = .21, t = 2.56, p < .05$, respectively), marital satisfaction ($\beta = -.19, t = -2.26, p < .05$ and $\beta = -.20, t = -2.34, p < .05$, respectively), and pain in the spouse ($\beta = .42, t = 5.18, p < .001$ and $\beta = .44, t = 5.37, p < .001$). Neither the main effects for helplessness and rumination nor the interaction terms were significant, $p$s < .05.

Table 4
Hierarchical regression predicting depressive symptoms from magnification, ICP pain severity, and spouses’ personal experiences with chronic pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>$B$</th>
<th>SE $B$</th>
<th>$\beta$</th>
<th>$t$</th>
<th>$R^2$</th>
<th>$\Delta R^2$</th>
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</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender of spouse</td>
<td>9.08</td>
<td>3.64</td>
<td>.20</td>
<td>2.50*</td>
<td>.47</td>
<td></td>
</tr>
<tr>
<td>Marital satisfaction</td>
<td>−.44</td>
<td>.10</td>
<td>−.34</td>
<td>−4.26***</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Magnification</td>
<td>−.30</td>
<td>.81</td>
<td>−.04</td>
<td>−.37</td>
<td>.58</td>
<td>.11**</td>
</tr>
<tr>
<td>Spouse pain</td>
<td>12.98</td>
<td>3.79</td>
<td>.29</td>
<td>3.45***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICP pain severity</td>
<td>.47</td>
<td>.43</td>
<td>.14</td>
<td>1.11</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnification × spouse pain</td>
<td>2.71</td>
<td>1.28</td>
<td>.24</td>
<td>2.11*</td>
<td>.62</td>
<td>.04</td>
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<tr>
<td>ICP pain severity × spouse pain</td>
<td>−.08</td>
<td>.59</td>
<td>−.02</td>
<td>−.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICP pain severity × magnification</td>
<td>.15</td>
<td>.11</td>
<td>.12</td>
<td>1.30</td>
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<td></td>
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<tr>
<td><strong>Step 4</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>ICP pain severity × spouse pain × magnification</td>
<td>.04</td>
<td>.22</td>
<td>.02</td>
<td>.20</td>
<td>.62</td>
<td>.00</td>
</tr>
</tbody>
</table>

Note. ICP, individual with chronic pain.
* $p < .05$.
** $p < .01$.
*** $p < .001$.

4. Discussion

Research has demonstrated that the interpersonal nature of chronic pain inevitably leads to negative consequences for both ICPs and others that are close to them. Borrowing from an empathy model of pain (Goubert et al., 2005), we examined both observer (i.e., top-down influences) and ICP (i.e., bottom-up influences) characteristics that may be important in affecting observers’ psychological distress.

ICP pain severity, a bottom-up variable, was related to spouse depressive symptoms as was expected. ICP pain severity may result in pain behaviors or other observable signs that cue the spouse as to how the ICP is feeling. Interestingly, ICP pain severity was not significantly associated with spouse anxiety symptoms in contrast to studies showing that pain severity is associated with anxiety in ICPs (Cano et al., 2004). Perhaps for spouses, witnessing a partner in pain is not associated with a high arousal state including fear or tension.

One top-down influence examined in the current study was spouses’ personal experiences with chronic pain. Spouses who experience pain themselves may have a greater appreciation for the difficulties ICPs may face (i.e., a greater sense of knowing; Goubert et al., 2005). Indeed, we found that spouses’ personal experience with chronic pain was associated with greater distress. In fact,

Table 5
Hierarchical regression predicting anxiety symptoms from magnification and spouses’ personal experiences with chronic pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>$B$</th>
<th>SE $B$</th>
<th>$\beta$</th>
<th>$t$</th>
<th>$R^2$</th>
<th>$\Delta R^2$</th>
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</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender of spouse</td>
<td>4.67</td>
<td>2.12</td>
<td>.18</td>
<td>2.20*</td>
<td>.32</td>
<td></td>
</tr>
<tr>
<td>Marital satisfaction</td>
<td>−.15</td>
<td>.06</td>
<td>−.20</td>
<td>−2.45*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnification</td>
<td>.15</td>
<td>.42</td>
<td>.03</td>
<td>.27</td>
<td>.54</td>
<td>.22**</td>
</tr>
<tr>
<td>Spouse pain</td>
<td>10.93</td>
<td>2.08</td>
<td>.42</td>
<td>5.26**</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnification × spouse pain</td>
<td>1.41</td>
<td>.67</td>
<td>.21</td>
<td>2.09*</td>
<td>.57</td>
<td>.03</td>
</tr>
</tbody>
</table>

* $p < .05$.
** $p < .001$. 

Note. ICP, individual with chronic pain.
almost half of the spouses reported a chronic pain problem. While this number may not be surprising because of the high prevalence of chronic pain (Bonica, 1990; Smith et al., 1999), few studies have investigated this matter. Past research that has examined spouses’ general health has shown that spouses of ICPs are more likely to have pain symptoms than spouses of patients with diabetes (Flor et al., 1987a). Additionally, spouses of depressed pain patients have more pain symptoms than spouses of depressed patients without pain (Mohamed et al., 1978). Mohamed et al. (1978) further noted that the location of the pain symptoms among spouses was more similar to patient’s pain location for this group compared to the depressed group without pain. Although that study lacked a group of participants who were not depressed but still had pain, the findings suggest some similarity within couples with pain. It is possible that some spouses of ICPs experience more physical wear and tear on their bodies due to additional responsibilities (e.g., household chores). Clearly, researchers should fully examine such top-down variables and not assume that all spouses of ICPs are physically healthy.

Spouses’ pain catastrophizing was also investigated as a top-down influence that relates to psychological distress because it could enhance or alter spouses’ knowledge about ICPs’ pain. Helplessness and magnification catastrophizing were correlated with depressive symptoms; however, several significant interactions suggested that more complex relationships existed when also accounting for the spouses’ personal experiences with pain. That is, magnification and helplessness catastrophizing were significant correlates of depressive symptoms in SCPs but not in spouses without chronic pain. The magnification results were also found for anxiety symptoms. These interactions are consistent with the framework presented earlier, and suggest that multiple top-down characteristics work together in influencing affective response to chronic pain. For instance, spouses who have personal experience with pain and magnify the ICPs’ pain may feel more depressed and anxious because it is difficult for them to pull their attention away from pain cues. Spouses who have pain and also engage in helplessness catastrophizing may have increased feelings of hopelessness and perceptions of caregiver burden. Not only is their sense of knowing about their partners’ pain increased but that sense of knowing might also contribute to catastrophizing about their own pain. Unfortunately, we did not assess spouses’ catastrophizing directed toward their own pain experience. Future research may be able to address the relative contributions of ICP-directed and self-directed pain catastrophizing in spouses. Such research could address the possibility that the negative effects of spouse catastrophizing are activated only when spouses experience pain. In addition, it is possible that psychological distress primes spouses to focus on negative aspects of their own and the ICPs’ pain problems. Additional longitudinal or experimental studies must be conducted to further explore the mechanisms and directions between the relationship of catastrophizing and psychological distress.

Helplessness catastrophizing did not interact with spouses’ personal experiences with chronic pain in associating with anxiety symptoms. Helplessness catastrophizing may not be a factor in anxiety symptoms because of the high arousal nature of these symptoms. Alternatively, helplessness catastrophizing may tap feelings of hopelessness and “giving up” rather than helplessness or feelings of threat, which might explain why this type of catastrophizing is related to depressive but not anxiety symptoms in spouses. In addition, rumination catastrophizing was not associated with depressive or anxiety symptoms. The content of the rumination items (i.e., “I keep thinking about how much it hurts my partner”) may reflect persistent thoughts about ICP pain as well as spouses’ care and concern for ICPs’ welfare. While creating sustained attention on the negative impact of the pain and increasing spouses’ sense of knowing about ICPs’ pain, rumination may result in a feeling of understanding of ICPs’ experiences. Therefore, while rumination catastrophizing may be experienced as unpleasant, it may not correlate with spouse distress. Perhaps, ruminative catastrophizing is associated with other spouse outcomes such as spouse solicitous responses to pain. Additional research is needed to further clarify this hypothesis.

Although the current study has contributed to the knowledge of the impact of pain on spouses, there are several limitations. First, the data used in the current study were cross-sectional in nature. Therefore, these data cannot be used to provide causal or temporal explanations. Additionally, data regarding the pain status of the spouse were based solely on the self-report and verification of pain by physician reports of medical information was not conducted. Spouses of ICPs may be primed to interpret physical sensations as pain because they are confronted with ICP pain almost daily. The current study asked spouses to report on their pain catastrophizing about pain in the ICPs. The extent to which SCPs catastrophize about their own pain is unknown. Finally, although we discuss the findings in the context of an empathy framework, empathy was not directly measured in the current study. To provide a complete test of the Goubert et al. (2005) model, researchers must examine empathy and how it relates to top-down and bottom-up characteristics as well as observers’ psychological distress and behavioral reactions.

In sum, the current findings provide support for the further exploration of top-down and bottom-up factors that contribute to observers’ experiences (Goubert et al.,
2005). The current study also emphasizes the need to include both partners in the assessment of chronic pain for research and treatment purposes. It is recommended that researchers interested in spouses of ICPS differentiate between SCPs and spouses without chronic pain to identify important processes that may account for psychological distress. Additionally, the interaction between top-down and bottom-up factors within couples and other close dyads (e.g., parents and children) should be explored as chronic pain clearly has interpersonal consequences.

References


Watson D, Clark L. Mood and anxiety symptom questionnaire, unpublished manuscript. University of Iowa, Department of Psychology: Iowa City, IA; 1991.

Efficacy and safety of a single botulinum type A toxin complex treatment (Dysport®) for the relief of upper back myofascial pain syndrome: Results from a randomized double-blind placebo-controlled multicentre study

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Abstract

Botulinum type A toxin (BoNT-A) has antinociceptive and muscle-relaxant properties and may help relieve the symptoms of myofascial pain syndrome. In this study we evaluated the efficacy and tolerability of BoNT-A (Dysport®) in patients with myofascial pain syndrome of the upper back. We conducted a prospective, randomized, double-blind, placebo-controlled, 12-week, multicentre study. Patients with moderate-to-severe myofascial pain syndrome affecting cervical and/or shoulder muscles (≥10 trigger points, disease duration 6–24 months) were randomized to Dysport® or saline. Injections were made into the 10 most tender trigger points (40 units per site). The primary outcome was the proportion of patients with mild or no pain at week 5. Secondary outcomes included changes in pain intensity and the number of pain-free days per week. Tolerability and safety were also assessed. At week 5, significantly more patients in the Dysport® group reported mild or no pain (51%), compared with the patients in the placebo group (26%; \( p = 0.002 \)). Compared with placebo, Dysport® resulted in a significantly greater change from baseline in pain intensity during weeks 5–8 (\( p < 0.05 \)), and significantly fewer days per week without pain between weeks 5 and 12 (\( p = 0.036 \)). Treatment was well tolerated, with most side effects resolving within 8 weeks. In conclusion, in patients with upper back myofascial pain syndrome, injections of 400 Ipsen units of Dysport® at 10 individualised trigger points significantly improved pain levels 4–6 weeks after treatment. Injections were well tolerated.

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Keywords: Myofascial pain syndrome; Botulinum toxin; Pain; Trigger point

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1. Introduction

Myofascial pain syndrome is a chronic musculoskeletal disorder caused by acute or chronic muscular stress (Yunus et al., 1988; Fischer, 1997). The condition is characterized by shortened or contracted muscles containing trigger points, which, on stimulation, transfer pain to surrounding areas (Wheeler, 2004). The pathology of myofascial pain syndrome remains elusive, but appears to involve a complex interaction of numerous pathogenic mechanisms including ischemia-induced muscle spasms, hyperactivity of the neuromuscular spindle or motor endplate, and peripheral or central sensory sensitisation (Hubbard and Berkoff, 1993; Quintner and Cohen, 1994; Simons, 1996; Berg-Stein and Simons, 2002; Mense et al., 2003).

Oral therapies, injection of local anaesthetics or sodium chloride, stimulation methods and physiotherapy have all been used to treat myofascial pain syndrome, but their efficacy tends to be unreliable and many are limited by side-effects (Baldry, 2002; Wheeler, 2004). Recently, injection of botulinum type A toxin (BoNT-A) has emerged as a potential new therapy for this disorder (Acquaro and Borodic, 1994; Cheshire et al., 1994; Porta et al., 1998; Göbel et al., 2001a,b; Göbel and Jost, 2003). BoNT-A has antinociceptive and muscle-relaxant properties and has been used successfully to treat chronic pain and a wide range of muscular disorders (Cordivari et al., 2004; Cui et al., 2004; Acquaro and Borodic, 2005; Dressler and Adib Saberi, 2005). Furthermore, BoNT-A may modulate the activity of muscle spindles, which may have particular relevance in myofascial pain syndrome (Filippi et al., 1993; Rosales et al., 1996).

Three small studies have shown a beneficial effect with BoNT-A treatment in patients with myofascial pain syndrome. In a small double-blind placebo-controlled study in six patients, trigger point injections of BoNT-A significantly reduced pain by over 30% in four patients, an effect that was absent with placebo (Cheshire et al., 1994). In a second study involving 33 patients, significantly more patients were asymptomatic after a single injection of BoNT-A (50 or 100 Dysport units) in the paraspinal cervicothoracic muscles compared with those who received saline (Wheeler et al., 1998). In a third study involving 40 patients, pain reduction after two months was significantly more pronounced with a single injection of BoNT-A than with methylprednisolone treatment (Porta, 2000).

Dysport®, a *Clostridium botulinum* type A toxin-contains, is a highly purified and highly potent form of BoNT-A. The drug is used for the treatment of numerous conditions, including muscle movement disorders and pain therapy, and novel indications continue to emerge. The objective of this study was to evaluate the efficacy and tolerability of Dysport® in patients with myofascial pain syndrome of the upper back. Our aim was to extend the observations of preceding studies, which had a limited sample size and investigated small doses of BoNT-A, to a larger patient population and a higher dose range. In addition, to try and maximise the therapeutic effects of BoNT-A, treatment was individualised for each patient, administering BoNT-A at the site of the most painful trigger points.

2. Methods

2.1. Study design

This was a prospective, randomized, double-blind, placebo-controlled multicentre study to investigate the efficacy and tolerability of a single Dysport® treatment in patients with upper back myofascial pain syndrome. Eligible patients were recruited between 29 April 2002 and 4 December 2003 at 15 hospitals and clinics based in Germany and Austria. All patients gave written informed consent prior to enrolment. The study was approved by an independent Ethics Committee and the Institutional Review Board at each participating site, and conducted in accordance with the Declaration of Helsinki (1996 amendment) and the principles of Good Clinical Practice.

2.2. Patients

Men and women aged 18–70 years, with myofascial pain syndrome affecting cervical and/or shoulder muscles, were eligible for the study. Patients were included into the study if they had at least 10 trigger points and a disease duration of 6–24 months. Eligible patients were those experiencing pain of moderate-to-severe intensity, which was defined as a mean weekly score of at least 3 points on an ordinal self-rating pain scale, rated from 1 (no pain) to 4 (severe pain). At the screening visit (week – 1), patients were given a physical examination and optional neurological/muscular tests (computed tomography scan, magnetic resonance imaging scan and/or electromyography test) to ensure there was no evidence of other specific disorders.

Patients who had previously received treatment with botulinum toxin were not included in the study. Patients were also excluded if they were likely to participate in another clinical trial during the current study or if they had been involved in another clinical trial within the 3 months prior to enrolment. Other exclusion criteria were: concurrent muscle disease, conditions associated with medication-induced bleeding, pregnancy or a risk of pregnancy, a history of drug or alcohol abuse, a body mass index of more than 30 kg/m² or specific back pain disorders. Certain concomitant medications were not permitted during the 4 weeks prior to treatment (opioids, invasive therapy methods or neuromuscular blocks in the region of treatment and parenteral or oral corticosteroids), during the week prior to treatment (non-steroidal anti-inflammatory drugs, topical antiarthemias, topical corticosteroids and muscle relaxants) or during the day prior to treatment (paracetamol or other analgesics; heat, massage, cold or rheumatism bath therapy).
2.3. Treatment protocol and randomization

Providing eligibility criteria were still met at visit 2 (week 0), patients were randomized to either BoNT-A (Dysport®; Ipsen Ltd, Slough, UK) or placebo (0.9% NaCl solution). Injections were made by the physician into the 10 most painful trigger points (40 Ipsen units per site). The physician identified these trigger points by palpation of the cervical and/or shoulder muscles. The identification was based on the operational definition of Simons (1996), all doctors were trained for standardized trigger point identification and data collection. Injections were made with 2.5 ml syringes, using a 27 gauge 40 mm needle, at an injection depth of 1–3 cm.

Patients were assigned to treatment in blocks using a computer-generated randomization schedule. The two study treatments were identical in appearance, colour, form, size, consistency, taste and odour, and both physicians and patients were blinded to the treatment used. Injections were prepared independently by a person not involved in the study, who opened the sealed envelope containing the randomization code and prepared the syringes accordingly with either active treatment or placebo. Investigators received a sealed envelope containing the randomization code for each patient, which was only to be opened in the event of an emergency. The randomization code was kept centrally, and unblinding took place after the end of the study, when all evaluations had been completed.

2.4. Assessments

At the screening visit, patients were given a physical examination, and body weight and vital signs were measured. Patients were also given a diary to record pain intensity each day, using the ordinal self-rating pain scale. They were asked to keep a daily record of their pain during the week prior to randomization and for 12 weeks after treatment. After the treatment visit, subsequent visits were scheduled every 4 weeks. During these visits vital signs, pain on palpation of cervical and shoulder muscles, concomitant diseases and therapies, adverse events (AEs) and diary compliance were recorded.

The primary outcome measure was the proportion of patients with mild or no pain at week 5 (responders), according to their mean score on the ordinal self-rating pain scale. Secondary outcome measures for efficacy included changes in pain intensity, duration of pain, the number of pain-free days per week, duration of sleep, the number and pain intensity of trigger points and the time to an improvement in pain. Global evaluation assessments were completed by the physician and patient. At the end of the study, the preference of the patient and physician for a repeated treatment was determined.

Safety was assessed by recording the number and nature of AEs, patient withdrawals, vital signs and patient/physician global assessments of tolerability.

2.5. Statistical methods

Sample size was calculated assuming a difference of 30% between active treatment and placebo (performed with Nidid, Gauting, Germany). Results indicated that two groups of 56 patients were required to detect an effect with 90% power and a two-sided type I error of 0.05. To account for drop-outs, the study plan recommended inclusion of 120 patients in total.

Patients with efficacy data were included in the intention-to-treat (ITT) population, patients without major protocol deviations were included in the per protocol (PP) population, and those that received study medication were included in the safety population. Efficacy data presented here are for the ITT population, and any differences between ITT and PP populations are noted. Where efficacy data were missing, analysis was carried out on a last observation carried forward basis.

Continuous variables were tabulated using summary statistics: number of values, mean, standard deviation, median, quartile ranges, minimum and maximum values and confidence intervals (where appropriate). Some continuous variables were categorized into grouped intervals and frequencies and percentages were calculated. Descriptive statistics were calculated using the Wilcoxon rank sum test (continuous data) or the Chi-squared test (frequencies and percentages). To test for baseline equivalence between the two treatment groups, the Wilcoxon–Mann–Whitney test was used and 90% confidence intervals were calculated. Differences in efficacy variables between the two groups were calculated using the Wilcoxon rank sum test (continuous data) or a two-tailed Fisher-exact test (frequencies and percentages). When multiple tests were conducted, the p-value was corrected using Bonferroni’s method. All statistical tests were two-sided and performed at the 5% level of significance.

3. Results

3.1. Patients

Patient flow through the study is shown in Fig. 1. A total of 145 patients were randomized to Dysport® (n = 75) or placebo (n = 70). All patients received study medication and were included in the safety population. One patient in the Dysport® group received medication but had no efficacy data so was included in the safety population, but not the ITT population. A total of 24 patients had major protocol deviations and were excluded from the PP population.

There were no significant differences between treatment groups in terms of demographic, physical, cardiovascular or neurological characteristics at baseline. Patients included in the study had a mean age of 45 years, were predominantly women (80%) and, on average, had suffered from myofascial pain syndrome for 19 months (Table 1).

3.2. Efficacy

At week 5, significantly more patients in the Dysport® group reported mild or no pain (51%), compared with the patients in the placebo group (26%; p = 0.002) (Fig. 2). These results were supported by analysis of the PP population. Over the entire study period, the number of responders was generally higher in the Dysport® group than in the placebo group, and this difference was significant during weeks 5, 6 and 11 (Fig. 3). Similarly, the change from baseline in pain

37
intensity over time was generally more pronounced for Dysport® than for placebo, with a significant difference between groups in weeks 5–8 (Fig. 4). During the period between week 5 and the study end, patients in the Dysport® group experienced significantly more days per week without pain ($p = 0.036$) and significantly more days per week with no or mild pain ($p = 0.023$), compared with patients in the placebo group.

Over the course of the study, there were neither significant differences between groups in the duration of daily pain nor the duration of sleep. There were also no significant differences between groups in the number of trigger points over the course of the study. However, the mean pain intensity scores for all trigger points were significantly lower with Dysport® than with placebo at week 4 ($p = 0.001$) and this benefit persisted until the end of the study ($p = 0.02$) (Fig. 5).

The physicians' global assessment of the patient's condition favoured Dysport® over placebo at week 4 ($p = 0.004$), week 8 ($p < 0.001$) and week 12 ($p = 0.003$). Similarly, patients' global assessment of their condition also favoured Dysport® over placebo at week 4 ($p = 0.03$), week 8 ($p = 0.002$) and week 12 ($p = 0.01$).

A significantly higher proportion of patients in the Dysport® group recommended a repeated treatment (55/67, 82%) compared with patients in the placebo group (39/65, 60%; $p = 0.007$). This trend was mirrored by the preferences of the physicians treating these patients. A significantly higher proportion of physicians treating patients that received Dysport® recommended a repeated treatment (59/66, 89%) compared with those treating patients that received placebo (43/63, 68%; $p = 0.004$).

### Table 1
Baseline demographic and clinical characteristics of the patients included in the intent-to-treat population

<table>
<thead>
<tr>
<th></th>
<th>Dysport® ($n = 74$)</th>
<th>Placebo ($n = 70$)</th>
<th>Difference</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>44 (12)</td>
<td>45 (11)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td>168 (8)</td>
<td>169 (7)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>70 (14)</td>
<td>72 (14)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>Sex, number of male patients</td>
<td>13 (18%)</td>
<td>16 (23%)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>Disease duration (months)</td>
<td>18 (6)</td>
<td>19 (9)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>Pain intensity (sum of all single scores)</td>
<td>32.7 (5.8)</td>
<td>32.5 (7.7)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>Duration of daily pain (h)</td>
<td>11.17 (0.66)</td>
<td>10.52 (0.78)</td>
<td>n.s.</td>
<td></td>
</tr>
</tbody>
</table>

All values are shown as mean (SD) range unless stated otherwise.
3.3. Safety

A total of 65 AEs were reported during the study. Of these, 46 AEs were experienced by 31 patients in the Dysport©/C210 group, and 19 AEs were experienced by 11 patients in the placebo group (p < 0.001 between groups). Most AEs were mild or moderate in severity (48/64, 75%; intensity rating not available for one AE). The most common AE was sore muscle in both the Dysport©/C210 group (27/46, 59%) and placebo group (7/19, 37%). Therefore in the first seven days after treatment, the muscle pain in the verum group increased slightly. No serious AEs occurred during the study. One patient in each treatment arm withdrew from the study due to an AE (sore muscles).

Analysis of AEs over time revealed that the majority of AEs in the Dysport©/C210 group were documented in week 4 (27/31, 87%; p < 0.001 for Dysport© versus placebo). However, these were short-lived and had resolved by week 8 (p = 0.565), continuing until week 12 (p = 0.719). Of the AEs that occurred in the Dysport© group, 27/46 (59%) were considered possibly or probably related to the study drug. The median time to appearance of these AEs was 7 days after injection and 9/27 (41%) of these AEs persisted for at least 34 days after treatment.

Systolic blood pressure was marginally lower in the Dysport© group compared with the placebo group, reaching significance by week 12 (p = 0.04). Other assessments of vital signs throughout the study showed no significant difference between groups for diastolic pressure or pulse.

4. Discussion

This is the largest study published to date investigating the treatment of upper back myofascial pain with...
BoNT-A. The results showed that, in patients reporting moderate-to-severe pain at baseline, a significantly higher number of patients experienced only mild or no pain 5 weeks after treatment with Dysport® compared with those who received placebo. Furthermore, decreases in overall pain intensity and pain intensity at trigger points over time were both significantly greater with Dysport® than placebo. The positive effect of treatment was generally observed 4–6 weeks after the injections. Treatment was well tolerated, with most side effects resolving within 8 weeks.

The ability of BoNT-A to block the release of acetylcholine is well known, and this effect is thought to play a key role in pain relief (Mense, 2004). However, evidence suggests that BoNT-A may also impart direct antinociceptive effects via a number of other mechanisms. For example, BoNT-A has been shown to block the neuronal release of substance P, glutamate and calcitonin gene-related peptide (McMahon et al., 1992; Ishikawa et al., 2000; Welch et al., 2000; Chuang et al., 2004; Durham et al., 2004; Aoki, 2005). These neurotransmitters and neuropeptides are thought to be involved in peripheral and central sensitisation and the perpetuation of chronic pain mechanisms. Other effects of BoNT-A on processes involved in the pain response include inhibition of wide dynamic range neuron activation and downregulation of c-fos expression in the dorsal horn (Aoki, 2005; Vemulakonda et al., 2005). Therefore, as well as causing chemodenervation of skeletal muscles, BoNT-A may directly inhibit the neurotransmission of pain signals from the periphery to the cortex. This formed the basis for our decision to administer BoNT-A injections directly into trigger points, maximising access to these nociceptive pathways in the periphery.

The results of our study confirm observations made in earlier studies, which showed beneficial effects of BoNT-A treatment among a smaller number of patients (Cheshire et al., 1994; Wheeler et al., 1998; Porta, 2000). After our study had been completed, two additional studies also reported results of BoNT-A treatment in patients with myofascial pain syndrome (Ferrante et al., 2005; Kamanli et al., 2005). A small study by Kamanli et al. compared treatment with BoNT-A injections (10–20 Botox units at 3 trigger points), lidocaine injections or dry needling in 29 patients with myofascial pain syndrome (Kamanli et al., 2005). After 4 weeks, BoNT-A and lidocaine, but not dry needling, led to significant reductions in pain and significant improvements in quality of life. BoNT-A also significantly improved levels of depression and anxiety. These data support the results of our study, which showed the timing of a beneficial effect to be about 4–6 weeks after treatment. Dysport® and Botox® are not bioequivalent. The dose relationship in cervical dystonia of Botox units and Dysport units equals approximately 1:3 (Ranoux et al., 2002).

A larger randomized, placebo-controlled 12-week study was published by Ferrante et al. (2005). In 132 patients with myofascial pain syndrome, BoNT-A or saline was injected directly into up to five trigger points. However, active treatment failed to show a significant improvement in pain compared with the placebo.

Several aspects of the experimental design used in this study may help to explain why the results of Ferrante et al. were in disagreement with our findings. Firstly, the criteria Ferrante et al. used to exclude patients on the basis of the number of trigger points (in total and at specific locations) restricted the study population to patients with less severe myofascial pain syndrome. For example, only patients with fewer than five active trigger points were included in the study. These patients had considerably less severe disease than those involved in our study, and some may have had syndromes that were only just clinically relevant. Secondly, in addition to the therapies being investigated, patients received heavy pharmacological treatment (high-dose amitriptyline, ibuprofen 800 mg four-times-daily, and acetaminophen as a rescue medication), as well as individual physiotherapy. Therefore, it is not surprising that in patients with relatively low disease severity, undergoing a complex pharmacological and physiotherapeutic treatment regimen, Ferrante et al. found little difference between BoNT-A and placebo.

The main limitation of our study was that the optimal dose of BoNT-A had not yet been established when the study was designed and, therefore, the dose we selected may not have been appropriate for all patients. Given the promising results seen using 400 Ipsen units of Dysport®, a dose–response study would help establish whether even better results could be achieved using a higher dose. It would also be useful to investigate whether a second set of injections would increase the therapeutic benefits observed with Dysport®.

![Fig. 5. Mean pain intensity scores for all trigger points throughout the study. Error bars represent SE.](image-url)
In conclusion, in patients with upper back myofascial pain syndrome, injections of 400 Ipsen units of Dysport® at 10 individualised trigger points significantly improved pain levels 4–6 weeks after treatment. Furthermore, injections were well tolerated, with most side effects resolving within 8 weeks. The benefits of treatment were reflected by the preferences of both investigators and patients, who were more likely to recommended a repeated treatment if they had received Dysport® than if they had received placebo.

References


LOCAL PERSPECTIVE: DION OPPERMANN
Botulinum Toxin type A is certainly an effective option in the more resistant Myofascial pain syndrome patients. The cost is the most limiting factor in its usage. In SA Botulinum Toxin is not reimbursed for its use in pain. At present Dysport® is not available in South Africa. Botox is the only Botulinum Toxin available locally. There is no easy way to convert the Dysport dosage to Botox units.
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The journal’s primary aim is the publication of review and original articles, case reports and letters to the editor aimed at specialist health care and other professionals working in pain as well as primary care practitioners. All material will be sent for peer review.

Manuscript preparation

1. Copies should be neatly typewritten, with double spacing and wide margins. The manuscript should be submitted either on disk or by email, photocopies alone are not acceptable. A further copy of the manuscript should be retained by the author. Authors are required to state that their material is original and not previously published or currently submitted elsewhere.

2. All abbreviations should be spelled out when first used in the text thereafter used consistently.

3. Scientific measurements should be expressed in SI units throughout, with two exceptions: blood pressure should be given in mmHg and haemoglobin values in g/dl.


5. Authors initials & surname, qualifications (e.g. MBBCH), position, affiliation & correspondence address to be set out in full on title page of article.

6. All articles (review, original research etc) are to have an abstract, giving a brief succinct overview of the article. The abstract should reflect the essence of the paper and be 200 to 250 words. For original research articles, the abstract should be structured as follows:- Background, methods, aim, results and conclusion.

7. Original research papers should be structured as follows:- Abstract (as per point 6), introduction, methods, results, discussion, conclusion and references (see references).

8. Authors must give a minimum of three key words, and should use the MeSH catalogue.

9. A clear statement on ethical issues in clinical and animal research must be provided; conflict of interest and patient confidentiality issues must be indicated.

Illustrations

1. Figures consist of all material which cannot be set in type, such as photographs and line drawings. (Table are not included in this classification and should not be submitted and photographs. Photographs should be glossy, unmounted prints. In no circumstances should original X-ray films be forwarded; glossy prints must be submitted.

2. Tables and legends for illustration should be typed and separate sheets and should be clearly identified. Table should carry Roman numerals, thus, I, II, III, etc, and illustrations Arabic numerals, thus: 1, 2, 3, etc.

3. Figure numbers should be clearly marked on the back of prints, and the top of the illustration should be indicated.

4. Where identification of a patients is possible from a photograph the author must submit a consent to publication signed by the patient, or by the parent or guardian in the case of a minor.

5. If any table or illustration submitted have been published elsewhere, written consent to republication should be obtained by the author form the copyright holder and the author(s).

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1. References should be inserted at the end of the sentence, outside the full stop, as superior numbers, and should be listed at the end of the article in numerical order. Do not list them alphabetically.

2. It is the author’s responsibility to verify references from the original sources.

3. References should be set out in the Vancouver style, and only approved abbreviations of journal titles should be used; consult the List of Journals Indexed in Index Medicus for these details. Names and initial of all authors should be given unless there are more than six, in which case the six names should be given followed by “et al”. First and last page numbers should be given.

Journal references should appear as follows:


4. “Unpublished observations” and “personal communications” may be cited in the text, but not in the references list. Manuscripts accepted but not yet published can be included as references followed by “(in press)”.

All manuscripts and correspondence should be emailed to:
Dr. Milton Raff at raffs@iafrica.com
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- Reduced rates and CPD points for attending PainSA congresses.
- Regional Group Symposia.
- Quarterly Journal of PainSA.

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THE AIM OF THE SOCIETY

To improve the Management of pain in all its aspects in South Africa

OBJECTIVES OF THE SOCIETY

- The objectives for which the Society is established are:
  - To promote an understanding amongst the health care community that the management of pain needs a team approach.
  - To promote co-operation between itself and hospitals, public and private institutions, government authorities, medical schemes, the health care professionals and the public generally.
  - To co-ordinate issues surrounding pain between itself and International groups with similar objectives.
  - To promote research into the diagnosis and treatment of pain.
  - To promote education at all levels in pain management.
  - To organise national, regional and local meetings.
  - To hold an Annual Pain congress.
  - To collect and administer funds for the furtherance of the above objectives.
  - To provide central co-ordination for the various groups involved in the management of pain in Southern Africa.

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Are you a registered Health Professional? Yes [ ] No [ ]

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Enclosed please find my annual subscription of R200 to be Member of PainSA

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For patients with chronic pain, administering fentanyl transdermally by means of patch adhered to the skin extends the duration of effect and is more convenient than using the parenteral route. The original fentanyl transdermal system (Durogesic® reservoir patch) consists of a drug reservoir containing fentanyl and ethanol gelled with hydroxyethyl cellulose. A rate controlled membrane controls fentanyl flux from the reservoir to the skin.

These patches have been replaced by a new matrix delivery system (matrix-TTS), in which the drug reservoir, permeation enhancer and rate controlling membrane have been replaced by an adhesive matrix. Fentanyl is dissolved in a novel polyacrylate adhesive to form a drug-in-adhesive layer, which, in conjunction with the stratum corneum provides the rate-controlling element in the percutaneous absorption of fentanyl. The matrix adheres directly to the skin, without adhesive edges or layers and the matrix patch is smaller than the reservoir system.

The bioavailability and pharmacokinetic profile of this patch, the Durogesic® D-TRANS Matrix Delivery System, is similar to that of the reservoir patch. However, clinical investigation has shown that there are specific benefits of the matrix system over the reservoir patch, in that patients reported better skin compatibility, adhesive properties, wearability and comfort when they were switched from the reservoir patch to the new matrix-TTS.

Forty six outpatients with chronic cancer pain or pain of non-cancer origin who were already being treated with a stable dose of transdermal fentanyl via the reservoir system were switched to a matrix-TTS with the same delivery rate. This patch was replaced with a new one after 72 hours which remained in place for a further three days.

Twenty three of the patients received no other analgesia, while the remainder received different combinations of non-steroidal anti-inflammatory drugs and adjuvants in addition to the fentanyl patch. The patients completed a diary to document pain intensity, sleep interference, adverse events and use of rescue medication in the preceding 24 hours. At the time of removal of each patch, they were also asked to rate skin-compatibility, adhesive property, wearing comfort and overall general satisfaction regarding the last patch, in terms of items such as skin-related issues, pain relief, handling and sleep interference. At the end of the study, they were asked to give a general impression of the new matrix patch system and to indicate whether they had a preference for either of the two patch delivery systems.

Pain scores, impact of pain on sleep and use of supplementary medication while using the matrix-TTS were similar to those at baseline. In general tolerability was also similar for the two patches, with the exception of pruritus, which appeared significantly less often during the second matrix patch. In the patient's self-assessment, the matrix-TTS scored significantly better after removal on days 6 and 9 for skin compatibility, adhesive properties, wearability and comfort, and general satisfaction compared to the reservoir patch. After removal of the reservoir patch, the skin at the application site was more frequently badly reddened, weeping, or blistered compared to when the matrix-TTS was used (33% vs. 6%). Final assessments of general satisfaction with the matrix-TTS showed it to be well accepted and efficacious with regard to pain relief and duration of analgesia. The majority of patients (67%) and physicians (71%) assessed the duration of analgesic efficacy to be equal to, or better than the reservoir system. Ninety one percent of patients preferred to continue using the matrix-TTS after completion of the study.

This study shows that switching outpatients from a fentanyl reservoir patch to a new matrix-TTS at the same delivery rate is simple, well accepted and safe without any dose titration or compromise in efficacy. However, the new matrix-TTS may provide greater comfort and be more acceptable to patients with chronic pain.