the current study aims: (a) in those with CWP, to document the long-term outcome of symptoms and identify predictors of persistence, and (b) in those free of CWP, to identify predictors of onset.

Methods: The original survey involved a random sample of subjects registered with two general practices, Subjects completed a postal questionnaire which included items on the site and duration of any pain during the past month, and concurrent symptoms (pain, fatigue, somatic and affective). Of the 2,105 who participated, 120 had died and 397 were no longer registered with the study practices in 1998. The remaining 1,588 subjects were sent a short questionnaire enquiring about the presence, site (shaded on a blank body manikin) and duration of any pain during the past month. Subjects were classified according to whether or not they satisfied the ACR definition for CWP. Associations between information collected at recruitment and onset/outcome are expressed as odds ratios (OR) with 95% confidence levels.

Results: 1,386 subjects completed the follow-up questionnaire (an adjusted response of 93%). Of those with CWP in 1991, 34% (n=59) still satisfied the definition seven years later. From the original survey, significant predictors for persistence were tiredness (OR4.8; 2.2–10.8), aged over 50 years (OR 3.0; 1.4–6.1) and somatic symptoms such as dry eyes/mouth (OR 3.5; 1.5–7.9). Of subjects reporting all three factors in 1991, 77% had persistent CWP in 1998. Thirteen percent (n=75) of subjects reported new CWP on follow-up. The strongest predictor of onset was originally reporting other pain (OR 4.8; 2.6–8.9).

Conclusion: This is the first long-term population study of CWP which demonstrates persistence of symptoms in a third of subjects, whom are distinguished by a small number of factors. New onset of CWP in the absence of previously reported pain is very uncommon.

References

382. Muscle metabolites detected in urine in fibromyalgia and chronic fatigue syndrome may suggest ongoing muscle damage
Rheumatology and **Psychological Medicine, Kings College Hospital and *Robert Steiner MRI Unit, Hammersmith Hospital, London, UK

Background: Creatine, the high energy phosphate buffer, has previously been shown to be a sensitive marker of muscle inflammation (measured in the urine) in myositis.

Methods: We assessed whether patients with fibromyalgia (FM) and chronic fatigue syndrome (CFS) showed evidence of ongoing muscle damage as measured by the loss of creatine in the urine. We measured urinary creatine by 1H-NMR spectroscopy and used Creatine/Creatinine ratio to adjust for hydration and muscle mass. We also measured several other metabolites known to be released in damaged muscle. First morning void urine samples were obtained from 60 patients with FM and 60 with CFS. Control groups included healthy controls n=12 and a variety of disease controls n=60.

Results: Significant levels of creatine were detected in the urine of 29 of 60 patients with FM and 32 of 60 patients with CFS compared to none of the healthy controls (both p<0.01) and 2 of the 60 disease controls. There was also significantly higher levels of urinary excretion of choline, taurine, citrate and trimethyl amine oxide in FM compared to controls (all p<0.05) and of choline and glycine in CFS compared to controls (both p<0.05).

Conclusions: This study reveals that approximately half these patients with FM and CFS were excreting creatine and other muscle related metabolites in their urine in detectable levels compared to healthy and disease controls. This may well represent ongoing muscle damage in FM and CFS and suggests a potential therapeutic target for dietary supplementation.

Soft Tissue Disorders – Back Pain and Treatment

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Background: ESWT has been used to treat numerous soft tissue lesions. We have previously reported a lack of effect of a low dose 3-month regime in lateral epicondylitis versus placebo. Here we report results from a study of a more intensive 3-week regime.

Methods: Adults with a clinical diagnosis of lateral epicondylitis participated. Basic characteristics were recorded. All subjects were randomised to blindly receive either ESWT (commencing at 1500 pulses at 3Hz and increasing to highest level tolerated) or sham at baseline, 1 & 2 weeks. At each visit, prior to treatment, global elbow pain and night pain were assessed by a blinded assessor using 100 mm visual analogue scores. Final follow up was performed within 1 month of completion.

Results: Results are presented for 25 adult subjects (13 females). All were chronic and resistant cases, most having received NSAIDs, physiotherapy and corticosteroid injection(s). The dominant arm was affected in 75% and 83% of cases in the ESWT and placebo groups, respectively. There was no significant difference in outcome with respect to night pain at any stage. Subjects in the placebo group improved more than those in the treatment group after two treatments but at final follow up 1–4 weeks after the course of 3 treatments, no significant differences existed between the two groups.

Table 1. Change in pain scores from baseline in Treatment and Placebo groups.

<table>
<thead>
<tr>
<th></th>
<th>Reduction in pain after 2 treatments</th>
<th>Reduction in pain after 3 treatments</th>
<th>Reduction in night pain after 2 treatments</th>
<th>Reduction in pain after 3 treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESWT</td>
<td>(19.6; ±17 to 45)</td>
<td>(19.3; ±17 to 50)</td>
<td>(12.9; ±29 to 26)</td>
<td>(17.3; ±53 to 13)</td>
</tr>
<tr>
<td></td>
<td>16.9</td>
<td>19.6</td>
<td>12.8</td>
<td>10.9</td>
</tr>
<tr>
<td>Placebo</td>
<td>(21.3; ±14 to 52)</td>
<td>(26.1; ±22 to 53)</td>
<td>(19.7; ±13 to 51)**</td>
<td>(23.9; ±24 to 43)</td>
</tr>
</tbody>
</table>

Non-parametric unpaired t test. **p<0.02. ve sign indicates worsening of pain

Discussion: A significant placebo effect was demonstrated. ESWT was not superior to placebo over short term follow up in the treatment of lateral epicondylitis. There is evidence that ESWT makes night pain worse in the early stages of treatment. The large SD in both outcome measures in both groups emphasises the need for large sample sizes in intervention studies for lateral epicondylitis.
384. Extracorporeal Shock Wave Therapy (ESWT) in Non-Calcific Rotator Cuff Tendinitis. A pilot double blind, randomised placebo controlled study of a 3-week regime

C.A. Speed, J.T. Wies, H. Humphreys, C. Richards, B.L. Hazleman
Rheumatology Research Unit, Addenbrooke's Hospital, Cambridge, UK

Background: Although ESWT has been demonstrated to be effective in calcific rotator cuff tendinitis, we have previously reported a lack of effect of a low dose 3-month regime in non-calcific rotator cuff tendinitis. Here we report results from a study of a more intensive 3-week regime.

Methods: Adults with a clinical diagnosis of rotator cuff tendinitis participated. Those with clinical tears were excluded. Baseline characteristics were recorded. All subjects were randomised to blindly receive either ESWT (commencing at 1500 pulses at 3Hz and increasing to highest level tolerated) or sham at baseline, 1 & 2 weeks. At each visit, prior to treatment, the Shoulder Pain and Disability Index (SPADI) and night pain (100 mm VAS) were recorded by a blinded assessor. Final follow up was performed within 1 month of completion.

Results: Results are presented for 18 adult subjects (10 females). All were chronic cases of similar duration, and most had received NSAIDs, physiotherapy and corticosteroid injection(s). The dominant arm was affected in 77% and 88% of cases in the ESWT and placebo groups, respectively. There was no significant difference between the groups with respect to change in disability, pain nor in night pain at any stage.

Table 1. Change in outcome measures from baseline in Treatment and Placebo groups. Mean (SD; range)

<table>
<thead>
<tr>
<th>Group</th>
<th>Reduction in SPADI after 2 treatments</th>
<th>Reduction in SPADI 1–4 weeks after 3 treatments</th>
<th>Reduction in night pain after 2 treatments</th>
<th>Reduction in pain 1–4 weeks after 3 treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESWT</td>
<td>14.7 (29.8; –33 to 77)</td>
<td>18.0 (35.5; –8 to 87)</td>
<td>12.3 (29.7; –10 to 81)</td>
<td>15.3 (40.6; –20 to 94)</td>
</tr>
<tr>
<td>Placebo</td>
<td>20.1 (31.4; –4 to 79)</td>
<td>23.6 (18.2; –7 to 47)</td>
<td>12.9 (27.5; 16 to 57)</td>
<td>10.1</td>
</tr>
</tbody>
</table>

Non-parametric unpaired t test. *p* sign indicates worsening of pain.

Discussion: No significant benefit from the use of shockwave therapy up in the treatment of non-calcific rotator cuff tendinitis over short term follow-up. A significant placebo effect was demonstrated. The large SD in both outcome measures in both groups emphasises the need for large sample sizes in intervention studies for rotator cuff tendinitis.

Reference

385. Pragmatic, primary care-based randomised trial for shoulder pain: do patients' treatment preferences affect outcome?

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2Staffordshire Rheumatology Centre, Stoke-on-Trent, The Haywood, UK

Background: In clinical trials where patients are not blind to their allocated treatment, outcome may be affected by patients’ pre-conceived opinions of the treatment’s efficacy. Hence, one important concern is whether the observed treatment effect is due only to the treatment’s physiological and pharmaceutical properties or if it is influenced by individual preference.

Objective: To examine patients’ initial treatment preferences in a multi-centre, pragmatic, randomised trial of steroid injection (I) versus physiotherapy (P) for shoulder pain presenting to primary care as they affect (i) functional outcome and (ii) future treatment preferences.

Methods: Nine general practices recruited 207 adults consulting with an episode of unilateral shoulder pain over a 22-month period. Disability scores and participants’ preferences for the two trial treatments were elicited at 2 points: a) prior to randomisation, and b) 6-months post-randomisation. A ‘good functional outcome’ was defined as at least a halving in the disability score at 6-months from that recorded at randomisation. Overall, the percentage of patients with a good outcome was similar in the two treatment arms (53% I, 60% P).

Results: Pre-randomisation preferences were: 83 (40%) for injection, 42 (20%) for physiotherapy and 82 subjects (40%) gave no preference. Functional outcome was poorer for subjects not expressing a preferred treatment compared to those who did (42% I, 54% P versus 59% I, 64% P). Outcome was best in those who expressed a preference but did not receive it (71% I, 68% P). In subjects who indicated a pre-randomisation preference and who experienced a poor functional outcome, 52% indicated that their preference had changed by 6 months. This compares with 42% whose preference changed after a good functional outcome. In subjects who indicated a pre-randomisation preference and who experienced a good functional outcome, those subjects who received their preferred treatment were twice as likely to maintain the same preference, at 6-month post-randomisation, as those who did not. Of subjects giving no pre-randomisation preference, those with a good outcome were much more likely to report the treatment received as their preferred treatment at 6-months (50%), than those with a poor outcome (18%).

Conclusions: People who express a preference appear to have a better overall response to treatment. In this study however, actually getting the preferred treatment did not confer any additional benefit. This may reflect lack of previous experience of the preferred treatment since post-treatment preferences were indeed influenced by the response to treatment.

386. Shoulder pain in primary care: a qualitative study to explore which factors influence patients’ choice of treatment

E. Carpenter

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Background: Trials investigating the management of musculoskeletal pain often show a large placebo response. For example a recent Dutch study [1] in primary care suggested that patient preference for injection influenced outcome for shoulder pain. We therefore explored this further using qualitative research methods (semi-structured interviews) within the context of a RCT comparing the effectiveness of a local steroid injection and physiotherapy for managing shoulder pain in primary care.

Methods: Patients were asked their preferred treatment on their enrolment into the RCT. On completion of the trial, twelve patients were purposively selected to participate in interviews exploring the reasons for their treatment choice and their general health beliefs and behaviour. Half the sample had received a steroid injection and half physiotherapy. Within each treatment group, two patients preferred an injection, two preferred physiotherapy and two had no preference. Transcriptions of the interviews were analysed using
open coding and the results presented focused on extracts of the original transcripts.

**Results:** Patients’ choices involved complex reasoning processes. Speed of action, previous experience and faith/belief in a treatment method were common themes used in decision making. Previous personal experience appeared to strongly influence choice and health behaviour. Patient preference for one treatment often reflected negative choice for the other. All the patients choosing physiotherapy believed in the self-efficacy of physiotherapy for future episodes thus avoiding the need to re-consult their GP. Firm beliefs in one method of treatment could be altered by a successful outcome with an alternative treatment but in some patients lay beliefs and theories were powerful enough to lead to non-compliance and may contribute to poor outcome.

**Conclusions:** Lay beliefs and theories can have a powerful effect of health behaviour, compliance with treatment and eventual outcome. Further studies are required to ascertain whether consideration of these beliefs and preferences when choosing treatment options maximises compliance and optimises outcome.

**Reference**


### 387. Exercise-based rehabilitation of back pain improves pain, function and occupational outcome – a retrospective analysis of 742 patients

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**Background:** Military patients presenting with back pain may be offered a programme of exercise-based rehabilitation provided by a multi-disciplinary team. The aims of the study were to: 1) Evaluate the effect of this programme by determining whether there was an improvement in reported pain, physical function and occupational outcome; 2) Examine whether type of injury has an effect on outcome and 3) Analyse for gender/age effects.

**Methods:** Patients at DSMRC were admitted into groups determined by symptom severity and underwent 5 hours per day of specific and general exercise for a minimum of 4 weeks. Data were collected at the start and end of this treatment period in 742 cases (male=667; female=75) and analysed retrospectively. The following were assessed: pain (visual analogue scale), spinal range of motion in flexion and extension (ROM), single leg raise angles on both legs (SLR’s), muscle endurance tests (MET’s) in flexion and extension and a timed 800 m walk/run (FAT). Occupational level was determined by a physician using a scale to grade outcome (FAA) where 1 = Fully fit for all trade and military duties and 5 = Unfit for all duties. Patients were split into 3 groups depending on whether they had evidence of disc prolapse (MBP) or fracture (F). Data were also analysed by gender and age on admission. A battery of non parametric statistical tests were used to test for differences.

**Results:** The median age was 30 yrs (IQR=25–36). With all data grouped, patients showed significant improvement in pain, ROM, SLR’s, MET’s, FAT and FAA (p<0.01). PID showed significantly less ROM on presentation compared to FAT and MBP (p<0.01). There were no significant differences in the change in test scores over the therapy period (p>0.01) between injury classifications. Females had significantly more pain, greater SLR’s and slower FAT times on admission (p<0.01). Older patients had significantly better FAA scores than younger patients (p<0.01).

**Conclusions:** The results show that this exercise-based programme improved pain, mobility and local muscle endurance and that this translated into improved functional and occupational outcome. There did not appear to be any difference in outcome between injury type although type of injury did seem to affect absolute function in certain areas on admission. That older patients seemed to have better occupational outcome may be a reflection of their less arduous jobs. This study supports the use of exercise-based rehabilitation in back pain although it does not ascertain the optimum treatment period.

### 388. An analysis of adverse events in 70 patients undergoing caudal epidural for the treatment of radicular symptoms

Y. Ioannou, R. Moottoo, A.B. Bhanji

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**Background:** Marked heterogeneity exists in the degree to which patients undergoing caudal epidural are observed post procedure. This in part stems from the paucity of evidence detailing the type and frequency of adverse events that may occur secondary to this procedure. We analysed our cohort of patients in a retrospective fashion in an attempt to more accurately define the type and frequency of side effects observed at our centre.

**Methods:** Since May 1999 a total of 104 caudal epidurals for the treatment of radicular pain have been performed at this centre. Of these 70 case notes were available detailing their clinical sequela post procedure. These were analysed retrospectively and adverse events recorded. The protocol for performing caudal epidurals at this centre is summarised as follows: patients are admitted to our Medical Day Unit on the morning of the epidural, baseline observations and informed consent in obtained. Assuming there are no contraindications, under aseptic technique utilising anatomical landmarks, the sacral hiatus is cannulated using a spinal needle. A 20 ml mixture of triamcinolone (2 mls (40 mg)) and marcaine (18 ml of 0.25%) is injected over 10 minutes. The patient’s pulse and Bp is measured immediately post procedure and every 30 minutes thereafter for a total of 6 hours.

**Results:** Out of 70 patients, 16 (22.8%) had an adverse event. 4/104 (3.8%) urinary retention, requiring catheterisation (all resolved within 24 hours); 8/70 (11.4%) asymptomatic hypotension after 2 hours – mean baseline Bp 130/82, mean Bp 2 hours post procedure 92/57 – all recovered by 4 hours; 5/70 (7.1%) numbness below the waist, 2 with intense burning sensation; 1 vaso-vagal episode 3 hours post procedure; 1 superficial skin abscess 3 weeks post injection which resolved with oral antibiotics. No dural punctures or epidural abscesses have occurred.

**Conclusion:** The frequency of urinary retention and fluctuations in Bp beyond the range of normal diurnal variation leads us to recommend that all patients undergoing such a procedure be observed in hospital for a minimum period of 6 hours. Larger, preferably controlled prospective studies are required to elucidate possible predictive factors that may define patients predisposed to developing an adverse reaction.

**BSR Young Investigator Award Winner**

### 389. The Kings Exercise Prescription Fibromyalgia Intervention Trial (KeepFit)

S.C.M. Richards, D.L. Scott

**Rheumatology, Kings College Hospital, London SE22 8PT, UK**

**Background:** Fibromyalgia (FM) is common and often disabling. Exercise has previously been shown to be of some therapeutic benefit, but previous studies have tended to be under powered,
Introduction: Chronic pain syndromes are difficult to manage status persisting at 1 year follow up. Very much better compared to 12/67 of the relaxation group (Chi square=4.98; DF=1; p=0.02). This benefit persisted at 1 year. Exercise was associated with significantly greater improvements in tender point counts, pain and FM impact questionnaire scores than relaxation.

Conclusions: Community based exercise prescription of group based aerobic exercise is a safe and effective treatment for fibromyalgia leading to significant benefits in self reported health status persisting at 1 year follow up.

390. Symptomatic benefit with procaine infusion in chronic pain syndromes
V. Saravanan, S. Malt, T.J. Daymond
Department of Rheumatology, Sunderland Royal Hospital, Sunderland SR4 7TP, UK

Introduction: Chronic pain syndromes are difficult to manage and patents often do not respond to conventional therapeutic interventions. Procaine infusion was developed as an empirical treatment for the relief of chronic pain and has given benefit to many patients.

Methods: Patients attending our Ambulatory Care Unit were asked to fill out a questionnaire on their response to treatment. An IV infusion of 0.1% Procaine and 500 ml of normal saline was given on 3.96 and the mean fatigue score was 3.63. There is an improvement in the pain scores after the second week with maximum benefit in the sixth week, mean difference 1.1, p<0.001 (95% confidence intervals 0.55 to 1.66). This effect gradually waned and the pain score was back to pre infusion levels after the tenth week. There is a similar pattern of improvement in the fatigue scores of lesser scale with a maximum benefit at 6 weeks. Mean difference 0.78, p<0.001 (95% confidence intervals at 0.28 to 1.28). Both pain and fatigue scores improved better in women than men but this could have been biased due to the smaller numbers of men (n=17).

Conclusion: Intravenous Procaine infusion statistically improved pain and fatigue in patients with chronic pain syndrome over a twelve week period. Procaine infusions are a valuable asset in the management of chronic pain. More studies are required to confirm these results.

391. Topical capsaicin in the treatment of allodynia
Natalie Horwood1, Vanessa Morris2, Joseph Cowan3
1Rheumatology Unit, Orpington Hospital, Kent, 2Centre for Rheumatology, University College Hospital, London, 3Royal National Orthopaedic Hospital, Middlesex, UK

Background: Allodynia is an unpleasant sensation provoked by mechanical light touch which can cause considerable distress to the patient. This may be a result of reduced sensory thresholds of Group C pain fibres which release substance P. Repeated applications of capsaicin to skin may cause desensitisation of these pain fibre terminals and thus a reduction in symptoms.

Method: In a double-blind vehicle controlled crossover pilot study, 9 patients with allodynia were treated with topical capsaicin cream (0.075%) or its vehicle four times daily, for a two week period. After a week washout period they were then treated with the alternative agent. Response to treatment was evaluated by 100 mm visual analogue scales (VAS) of pain, together with an observers evaluation of response to a coton-tipped probe and von Frey hair.

Results: 5 females and 4 males were included in the study group. Mean age was 48 years (range 24–72 years) and mean duration of symptoms 6 years (range 2–10 years). 8 patients had allodynia secondary to trauma or surgery and 1 patient had primary disease. After 2 weeks of application, 66% of patients in the capsaicin group had improvements in their VAS scores for pain compared to baseline. 44% of those applying the vehicle alone showed improvements. These results failed to reach statistical significance.

Discussion: Allodynia is a distressing condition which is difficult to treat successfully despite a large armoury of potential therapeutic agents. This small scale pilot study has shown the capsaicin cream may have a place in some cases. A larger trial with longer duration of cream application is needed to fully elucidate the possible benefits of this treatment.