INSIDE THIS ISSUE:

Chronic Knee Pain  2
Neuralgia Pain  3
Juvenile Idiopathic Arthritis  4

PRESCRIPTION COMPOUNDING FOR

PAIN MANAGEMENT

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CHRONIC KNEE PAIN

The results of following study support advising older people with knee pain to use topical rather than oral NSAIDs - “Topical or oral ibuprofen for chronic knee pain in older people. The TOIB study” (Health Technol Assess. 2008 May;12(22):iii-lv, ix-155).

OBJECTIVE: To determine whether GPs should advise their older patients with chronic knee pain to use topical or oral non-steroidal anti-inflammatory drugs (NSAIDs).

DESIGN: An equivalence study was designed to compare the effect of advice to use preferentially oral or topical ibuprofen (an NSAID) on knee pain and disability, NSAID-related adverse effects and NHS/societal costs, using a randomised controlled trial (RCT) and a patient preference study (PPS). Reasons for patient preferences for topical or oral preparations, and attitudes to adverse effects, were explored in a qualitative study.

SETTING: Twenty-six general practices in the UK.

PARTICIPANTS: Participants comprised 585 people with knee pain, aged 50 years or over; 44% were male, mean age 64 years. The RCT had 282 participants: 144 in the oral group and 138 in the topical group. The PPS had 303 participants: 79 in the oral group and 224 in the topical group.

INTERVENTIONS: Advice to use preferentially oral or topical NSAIDs for knee pain.

RESULTS: Changes in the global WOMAC score at 12-months were equivalent in both studies: topical - oral, RCT difference=2 [95% confidence interval (CI) -2 to 6], PPS difference=1 (95% CI -4 to 6). There were no differences in the secondary outcomes, except for a suggestion, in the RCT, that those in the topical group were more likely to have more severe overall pain and disability as measured by the chronic pain grade, and more likely to report changing treatment because of inadequate pain relief. There were no differences in the rate of major adverse effects but some differences in the number of minor ones. In the RCT, 17% and 10% in the oral and the topical group, respectively, had a defined respiratory adverse effect (95% CI of difference -17% to -2.0%); after 12 months, the change in serum creatinine was 3.7 mmol/l (95% CI 0.9 to 6.5) less favourable in the oral than in the topical group, and 11% of those in the oral group reported changing treatment because of adverse effects compared with 1% in the topical group (p=0.02). None of these differences were seen in the PPS. Oral NSAIDs cost the NHS 191 pounds and 72 pounds more per participant over 1 year in the RCT and PPS respectively. In the RCT the cost per QALY in the oral group, from an NHS perspective, was in the range 9000-12,000 pounds. In the PPS it was 2564 pounds over 1 year, but over 2 years the oral route was more cost-effective. Patient preference for medication type was affected by previous experience of medication (including adverse reactions), other illness, pain elsewhere, anecdotes, convenience, severity of pain and perceived degree of degeneration. Lack of understanding about knee pain and the action of medication led to increased tolerance of symptoms. Potentially important symptoms may inadvertently have been disregarded, increasing participants' risk of suffering a major adverse effect.

CONCLUSIONS: Advice to use either oral or topical preparations has an equivalent effect on knee pain, but oral NSAIDs appear to produce more minor adverse effects than topical NSAIDs. Generally, these results support advising older people with knee pain to use topical rather than oral NSAIDs. However, for patients who prefer oral NSAID preparations rather than a topical NSAID, particularly those with more widespread or severe pain, the oral route is a reasonable treatment option, provided that patients are aware of the risks of potentially serious adverse effects from oral medication. Further research is needed into strategies to change prescribing behaviour and ensure that older patients are aware of the potential risks and benefits of using NSAIDs. Observational studies are needed to estimate rates of different predefined minor adverse effects associated with the use of oral NSAIDs in older people as are long-term studies of topical NSAIDs in those for whom oral NSAIDs are not appropriate. PMID: 18505668


BACKGROUND: Topical ibuprofen provides an alternative treatment to oral ibuprofen for the treatment of chronic knee pain.

OBJECTIVE: To compare the efficacy of topical versus oral ibuprofen in chronic knee pain treatment.

STUDY DESIGN: Prospective, randomized, unblinded pilot study.

SETTING: A private pain management practice.

METHODS: Twenty patients received either ibuprofen tablets 3 times daily (2400 mg total) or 4% topical gel 4 times daily (320 mg total) for 2 weeks. Subjects completed the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, the Medical Outcomes Study 12-Item Short Form (SF-12v2) Health Survey, and a satisfaction questionnaire.

RESULTS: Comparison of WOMAC and SF-12v2 mean changes from baseline showed no differences between groups. Patient satisfaction and study treatment convenience were rated equivalently between groups. Within the topical group, significant improvements (P < 0.05) were experienced in the mean differences of WOMAC Pain scores from baseline to 2 weeks (-82.6, -158.3 to -6.8), WOMAC Stiffness scores from baseline to one week (-25.3, -50.0 to -0.6) and baseline to 2 weeks (-47.8, -95.7 to 0.1), WOMAC Physical Function scores from baseline to one week (-175.9, -348.6 to -3.2) and baseline to 2 weeks (-312.1, -580.5 to -43.7), and patient satisfaction scores from baseline to one week and baseline to 2 weeks. Within the oral group, significant improvements (P < 0.05) were experienced in mean differences of WOMAC Physical Function from baseline to one week (-342.6, -638.1 to -47.1) and baseline to 2 weeks (-323.2, -637.1 to -9.2).

LIMITATIONS: As this was a preliminary investigation, the sample size of 20 subjects is a limitation in this study.

CONCLUSION: Treatment of chronic knee pain with topical ibuprofen provided comparable clinical efficacy and patient satisfaction as oral ibuprofen in this pilot study. PMID: 20859315

With our state of the art compounding lab we have the ability to compound ibuprofen into a topical cream at strengths to meet the unique needs of each of your patients.

COMPOUNDED MEDICATION

Ibuprofen 25%
Transdermal Cream
60gm
Apply to affected knee(s) Q4-6H PRN
NEURALGIA PAIN

Neuralgia is a common cause of pain and the following studies discuss which drugs effectively treat classic and symptomatic neuralgia pain.


**ABSTRACT:** “Trigeminal neuralgia is sudden, usually unilateral, severe, stabbing, brief recurrent pain in the distribution area of one or more of the branches of trigeminal nerve. Various pharmacological agents including carbamazepine, oxcarbazepine, phenytoin, lamotrigine, baclofen and clonazepam have been tried with variable success rate. Here a case of idiopathic trigeminal neuralgia is presented. The patient presented in the emergency room with severe pain in the distribution area of maxillary branch of trigeminal nerve, resistant to conventional pharmacotherapy, **managed successfully with gabapentin** without untoward side-effects.” PMID: 18705259

“Preliminary report: the efficacy of clonidine hydrochloride ointment for postherpetic neuralgia” (Masui. 2001 Feb;50(2):160-3).

**ABSTRACT:** “The combination of clonidine hydrochloride, alpha 2-agonist, and opioid is useful for relieving the pain due to surgical procedures or cancer. The routes of administrations used are intravenous, intramuscular as well as intrathecal, epidural and transmucosal. However, transdermal clonidine has not been reported. We, therefore, investigated the **analgesic effect of local administration of clonidine ointment**. Ten patients with postherpetic neuralgia (PHN) were selected randomly. They were requested to fill out a questionnaire after applying clonidine ointment (150 micrograms/ointment 1 g) to the painful area. Items included in the questionnaire were: effectiveness, visual analog scale (VAS) before and after the administration of clonidine ointment, onset time, with or without allodynia and effectiveness to allodynia in the former case, side effects, and patients’ background. Analysis of the answers indicates that clonidine ointment produced a satisfactory effect in nine patients. Onset time was within a few minutes in most patients. No patients suffered any side effects. Specific mechanism of effectiveness or the site affected has not been confirmed in this study, but considering the quick onset, it is presumed that the site where the ointment was applied was the very site that was affected. Clonidine hydrochloride ointment was effective in relieving the symptoms of PHN.” PMID: 6372646


**ABSTRACT:** “A double-blind crossover study of the effects of baclofen was conducted on 10 patients with typical trigeminal neuralgia. Baclofen significantly decreased the number of painful paroxysms in 7 of the 10 patients. An open trial in another 50 patients with trigeminal neuralgia refractory to or unable to tolerate carbamazepine showed that 37 (74%) were relieved of their attacks by baclofen, either alone (12 patients) or in combination with previously ineffective doses of carbamazepine or phenytoin (25). On long-term follow-up of one to five years (mean, 3.0 years), 18 of the 60 patients (30%) continued pain free while receiving baclofen; 10 (17%) went into remission after 3 to 6 months; 13 (22%) became refractory to baclofen after 1 to 18 months; and 2 (3%) elected operation despite a good response to baclofen. The results indicate that **baclofen is a useful drug in the treatment of trigeminal neuralgia**.” PMID: 6372646

We have the ability to combine gabapentin, clonidine, and baclofen into one transdermal cream which can be applied directly to the site of pain; potentially limiting the systemic side effects associated with the oral use of these medications and increasing patient compliance.

**COMPOUNDED MEDICATION**

<table>
<thead>
<tr>
<th>Gabapentin 10% / Baclofen 2% / Clonidine 0.2% Transdermal Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>120gm</td>
</tr>
<tr>
<td>Apply locally BID-TID PRN</td>
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JUVENILE IDIOPATHIC ARTHRITIS

The following study concludes that methotrexate produces a significant improvement across a wide range of health-related quality of life components in patients with JIA -“Methotrexate improves the health-related quality of life of children with juvenile idiopathic arthritis” (Ann Rheum Dis. 2008 Mar;67(3):309-14).

OBJECTIVES: To examine the change in health-related quality of life (HRQOL) and its determinants in children with juvenile idiopathic arthritis (JIA) treated with methotrexate (MTX).

METHODS: Patients were extracted from the PRINTO clinical trial which aimed to evaluate the efficacy and safety profile of MTX administered in standard, intermediate or higher doses (10, 15 and 30 mg/m²/week respectively). Children with polyarticular-course JIA, who were less than 18 years and had a complete HRQOL assessment were included.

RESULTS: A total of 521 children were included. At baseline, patients with JIA showed poorer HRQOL (p<0.01) than healthy children. In 207/412 (50%) and 63 (15%) children, HRQOL values were 2 standard deviations below the mean of healthy controls in the physical and psychosocial summary scale, respectively. After 6 months of treatment with standard dose MTX, there was a statistically significant improvement in all HRQOL health concepts, particularly the physical ones. Similar improvements were observed in those who did not respond to a standard dose of MTX and were subsequently randomised to a higher dose. The presence of marked disability at baseline was associated with a fivefold increased risk of retaining poor physical health after 6 months of active treatment with standard dose MTX. Other less important determinants of retaining poor physical well-being were the baseline level of systemic inflammation, pain intensity and an antinuclear-antibody-negative status.

CONCLUSION: MTX treatment produces a significant improvement across a wide range of HRQOL components, particularly in the physical domains, in patients with JIA. PMID: 17875547

With our state of the art compounding lab we have the ability to compound methotrexate into a flavored oral liquid that may be easier to administer and receive than tablets. We also have the ability to dose the medication to meet the needs of each of your patients.

An example of how you might prescribe follows:

**Compounded Medication**

Methotrexate 2mg/ml
Flavored Oral Liquid
QS
Give as directed
**Chronic Knee Pain**

- **[ ] Ibuprofen 25%**  
  Transdermal Cream  
  Quantity 60gm  
  Directions: Apply to affected knee(s) Q4-6H PRN

**Neuralgia Pain**

- **[ ] Gabapentin 10%/Baclofen 2%/Clonidine 0.2%**  
  Transdermal Cream  
  Quantity 120gm  
  Directions: Apply locally BID-TID PRN

**Juvenile Idiopathic Arthritis**

- **[ ] Methotrexate 2mg/ml**  
  Flavored Oral Liquid  
  Quantity QS _______ml  
  Directions: Give as directed

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**Directions**

_________________________________________________________________________________________________________

_________________________________________________________________________________________________________

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Prescriber’s Signature_________________________  Refills: 1 2 3 4 5 6 7 8 9 10 11 12 NR

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