Review: a single dose of oral naproxen or naproxen sodium reduced acute postoperative pain in adults

Mason L, Edwards JE, Moore RA, *et al*. Single dose oral naproxen and naproxen sodium for acute postoperative pain. *Cochrane Database Syst Rev* 2004;(4):CD004234.

Q Is a single dose of oral naproxen or naproxen sodium effective and safe for acute postoperative pain in adults?

METHODS

Data sources: *Cochrane Library* (Issue 4, 2002), Medline and PreMedline (1966–2002), PubMed (1966–2002), EMBASE/Excerpta Medica (1980–2002), Oxford Pain Relief Database (based on 40 hand searched journals from 1954–94), unpublished trials held in house, and reference lists of retrieved articles.

Study selection and assessment: published and unpublished randomised, double blind, clinical trials in any language that compared a single oral dose of naproxen or naproxen sodium with placebo (≥10 patients/group) in adults (≥12 y) with moderate to severe pain after a surgical procedure in a day surgery or inpatient setting; pain intensity had to be assessed 4–6 hours after initial administration using a validated pain measurement scale (ie, 5 point pain relief scale, 4 point pain intensity scale, or a 10 cm visual analogue scale for pain relief or pain intensity). 2 reviewers independently assessed individual study quality using the 3 item scale developed by Jadad *et al*.

Outcomes: included patients with ≥50% pain relief over 4–6 hours and patients with ≥1 adverse event.

MAIN RESULTS

10 trials (n = 996, age range 14–72 y) met the selection criteria. 68% of patients had dental surgery, and the remaining patients had either orthopaedic or general surgery. All trials had quality scores ≥3 out of 5. Meta-analysis was done using a fixed effects model and intention to treat data. More patients who received naproxen sodium, 550 mg, 440 mg, or 220 mg, or naproxen, 400 mg or 200 mg, had ≥50% pain relief at 4–6 hours after surgery compared with placebo (table). Naproxen sodium, 550 mg, did not differ from placebo for number of patients reporting ≥1 adverse event (table).

CONCLUSION

A single dose of oral naproxen sodium, 550 mg (equivalent to naproxen, 500 mg) or 440 mg (equivalent to naproxen, 400 mg), reduced acute postoperative pain in adults more than placebo.

For correspondence: Dr R A Moore, c/o Pain Research Unit, Churchill Hospital, Oxford, UK. andrew.moore@pru.ox.ac.uk

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Commentary

Pain remains undertreated in postoperative settings[1] despite evidence of the effectiveness of specific treatments. In determining the efficacy, duration of action, and adverse effects of naproxen, a commonly prescribed non-steroidal anti-inflammatory drug (NSAID), the review by Mason *et al* presents clinicians with an alternative treatment to opioids for moderate to severe postoperative pain. The review addresses concerns about respiratory depression and impaired gastric motility associated with opioids.[2] In considering this alternative, however, clinicians need to balance the benefits of opiate-sparing effects and the possibility of adverse effects.

Individuals have varying pain tolerances and may respond dissimilarly to different NSAIDs. The review provides comprehensive information on the effects of a single dose of naproxen or naproxen sodium—information that will be useful to clinicians managing patients who fail to respond to other prescribed NSAIDs or are prescribed lower or higher doses of naproxen or naproxen sodium.

Importantly, the meta-analyses showed significant pain relief with single dose usage. As well, the weighted mean time to remedication was 7.5 hours with naproxen sodium, 550 mg, compared with 2.6 hours with placebo. During heavy clinical workloads, less frequent medication requirements could help nurses to improve pain management and benefit patients who often wait for long periods after assessment for administration of pain medication. Although it is not uncommon to use a cut point of 50% pain relief in analyses of treatment effects, nurses should remember the subjective nature of pain and the potential negative effects of lower levels of pain on activities of daily living in some patients with lower pain thresholds. This again underscores the need for individual pain assessment.

The systematic review by Mason *et al* also highlights the inadequacy of available data on adverse events. Future studies of pain management need to include clear detailed reporting of patient withdrawals by treatment group.

Tracey Bucknall, RN, PhD
University of Melbourne
Melbourne, Victoria, Australia

1 Dolin SJ, Cashman JN, Bland JM. *Br J Anaesth* 2002;**89**:409–23.
2 *British National Formulary*. No 48. September 2004. http://www.bnf.org/bnf/bnf/48//openat/search.htm?b=2&q=%22opioids%22. Accessed 14 January 2005.

Naproxen sodium (NapS) or naproxen (Nap) *v* placebo for acute postoperative pain in adults*

Outcome at 4–6 hours	Number of trials (n)	Drug and dosage	Weighted event rates (NapS/Nap *v* placebo)	RBI (95% CI)	NNT (CI)
≥50% pain relief	6 (n = 500)	NapS, 550 mg	50% *v* 12%	318% (193 to 497)	3 (3 to 4)
	3 (n = 334)	NapS/Nap, 440/400 mg	50% *v* 11%	380% (175 to 738)	3 (3 to 4)
	2 (n = 202)	NapS/Nap, 220/200 mg	44% *v* 16%	187% (60 to 415)	4 (3 to 6)
				RRR (CI)	
≥1 adverse event	5 (n = 392)	NapS, 550 mg	24% *v* 27%	11% (−25 to 37)	NS
				RRI (CI)	**NNH (CI)**
	2 (n = 257)	NapS/Nap, 440/400 mg	22% *v* 17%	32% (−22 to 124)	NS
	1 (n = 122)	NapS/Nap, 220/200 mg	26% *v* 12%	121% (−10 to 443)	NS

*NS = not significant; other abbreviations defined in glossary. Weighted event rates, RBI, RRR, RRI, and CI calculated from data in article (based on a fixed effects model).