










Aspirin, 1000 mg, reduced moderate to severe pain in acute migraine headache

Lipton RB, Goldstein J, Baggish JS, *et al.* Aspirin is efficacious for the treatment of acute migraine. *Headache* 2005;**45**:283–92.

Q Is a single dose of aspirin, 1000 mg, effective for treatment of acute migraine with moderate to severe pain intensity?

METHODS

-  **Design:** Randomised, placebo controlled trial.
-  **Allocation:** unclear concealment.
-  **Blinding:** blinded (patients).
-  **Follow up period:** several time points up to 24 hours.
-  **Setting:** USA.
-  **Patients:** 485 patients who were 18–50 years of age (mean age 37 y, 79% women, 77% white); had experienced migraine headache, with or without aura, according to International Headache Society (IHS) criteria; had at least moderate pain; and had ≥ 1 but ≤ 6 migraines per month during the previous year. Exclusion criteria included vomiting $\geq 20\%$ of the time during an attack; initiation of preventive medication in the past 3 months or use of alkaloids to treat migraine; use of anticoagulant, gout, or arthritis medications; and previous non-responsiveness to medication for migraine.
-  **Intervention:** all patients were trained to identify a qualifying migraine attack (based on IHS criteria). Patients who had a qualifying migraine (with or without aura) of at least moderate intensity pain were instructed to take the study medication: 243 were allocated to aspirin, 1000 mg (Extra Strength Bayer Aspirin Caplets, Bayer Consumer Care Division, Morristown, NJ), and 242 were allocated to matched placebo. Patients were encouraged to wait ≥ 2 hours before taking rescue medication.
-  **Outcomes:** primary outcomes were headache response at 2 hours (change in pain intensity [4 point scale] from moderate or severe at baseline to mild or none) and freedom from pain. Other outcomes included reduction in symptoms of nausea, photophobia, and phonophobia; improvement in functional ability; and adverse events. Outcomes were based on patient self report diaries completed at 30 minutes, and 1, 2, 3, 4, 5, 6, and 24 hours.
-  **Patient follow up:** 401 patients (83%) who took the study medication and had confirmed migraine were included in the analysis.

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MAIN RESULTS

At 2 hours, more patients who received aspirin had a response and were pain free compared with patients who received placebo (table). Pain intensity difference scores were higher in the aspirin group from 1 hour onward. At 2 hours, more patients in the aspirin group had resolution of photophobia and phonophobia; the groups did not differ for resolution of nausea (table). More patients in the aspirin group had improved functional ability from 1–6 hours ($p < 0.001$). The groups did not differ for overall adverse events (table).

CONCLUSION

Aspirin, 1000 mg, reduced pain, photophobia, and phonophobia in appropriately selected patients with moderate to severe acute migraine pain.

Commentary

Migraine headaches are characterised by debilitating, unilateral, throbbing pain aggravated by routine activity and associated with nausea, vomiting, photophobia, and phonophobia.¹ An estimated 12% of the population have migraines, and more than half of patients treat this condition with over-the-counter (OTC) medication.² Lipton *et al* offer a needed evaluation of aspirin in caplet form for acute migraine. Notably, the study sample did not exclude patients bedridden by migraine, a common limitation of previous OTC migraine medication trials.

The authors reported that aspirin was statistically superior to placebo for most reported migraine pain and symptom endpoints. However, the clinical effects of treatment translate more modestly to 18% more responders and 14% more pain-free patients compared with placebo at 2 hours, with wide confidence intervals noted for numbers needed to treat (abstract table). Furthermore, 80% of patients who took aspirin still had at least mild pain at 2 hours, and recurrence rates at 6 and 24 hours were not different between groups. Marked attrition (173/401) at the 24 hour recurrence endpoint and the lack of a crossover design, as recommended by the IHS, were 2 noted study limitations.

Health professionals need to ensure that symptoms of acute migraine are differentiated from other serious health conditions such as hypertension or brain tumour, recognise the limitations of OTC medications for treating chronic or severely debilitating migraine attacks, and be aware of the potential for medication-induced headaches and other side effects if OTC treatments are overused. With these considerations in mind, the study by Lipton *et al* supports the recommendation of a 1000 mg dose of caplet form aspirin in appropriately selected patients as an inexpensive, potentially beneficial OTC treatment option for patients with acute migraine headache.

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1 Wenzel RG, Sarvis CA, Krause ML. *Pharmacotherapy* 2003;**23**:494–505.
2 Lipton RB, Stewart WF, Diamond S, *et al.* *Headache* 2001;**41**:646–57.

Aspirin, 1000 mg, v placebo for acute migraine with moderate to severe pain*

Outcomes at 2 hours	Aspirin	Placebo	RBI (95% CI)	NNT (CI)
Response†	52%	34%	53% (21 to 94)	6 (4 to 12)
Pain free	20%	6%	233% (83 to 513)	8 (5 to 14)
Resolution of nausea	52%	43%	21% (-2 to 49)	Not significant
Resolution of photophobia	30%	14%	114% (44 to 221)	7 (5 to 13)
Resolution of phonophobia	34%	17%	100% (40 to 188)	6 (4 to 12)
			RRI (95% CI)	NNH
Any adverse event over 24 hours	8.8%	4.9%	79% (-14 to 273)	Not significant

*Abbreviations defined in glossary; RBI, RRI, NNT, NNH, and CI calculated from data in article.
†Response = change in pain intensity from moderate or severe at baseline to mild or none.