

# TWO-PHASE OPEN-LABEL STUDY OF LEVETIRACETAM IN THE MANAGEMENT OF INTRACTABLE HEADACHE

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## ABSTRACT

### OBJECTIVE of the Study:

To compare slow and fast titration of levetiracetam for the treatment of intractable headache.

### DESIGN:

84 patients were treated with a rapid titration schedule increasing levetiracetam dosage by 500 mg every five days to a level of 1500 to 2000mg. In the second phase of this study, an additional 88 patients were treated with a slower titration scale beginning with 250mg added weekly to a similar dosage.

### SETTING:

Outpatient Neurology Clinic.

### PATIENTS:

172 patients with intractable headache. Intractable headache was defined as patients who had previously failed three or more preventative regimens.

### MAIN OUTCOME MEASURES:

Headache Improvement Scale. Patients rated their headache improvement on a scale of 1 to 5: (1=No improvement, 2=Minimal improvement, 3=Moderate improvement, 4=Good improvement, 5=Excellent improvement).

### CONCLUSION (Results):

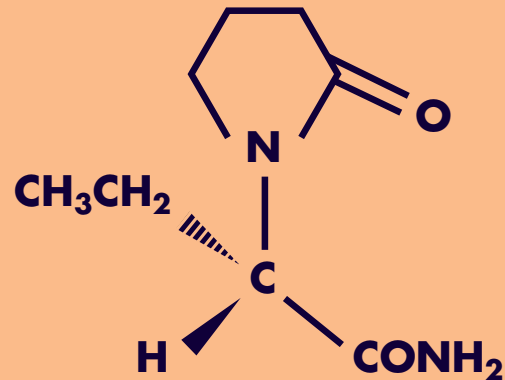
68 of the original 84 patients' data were available for analysis. A significant number of patients did not continue their medication because of the high initial cost. 30 patients stopped taking levetiracetam because of drowsiness or other side effects. 28 patients noted improvement and, in some, improvement was dramatic (Level 5).

In the second phase of the study (slow titration) only 10% of the patients stopped taking the medication secondary to drowsiness or other side effects. 70% of the patients experienced significant relief (Level 3 or higher).

### SUMMARY:

172 patients with intractable headaches were treated with levetiracetam. A slow titration schedule was much better tolerated and a dosage range of 1500mg to 3000mg was usually necessary to control chronic daily headache.

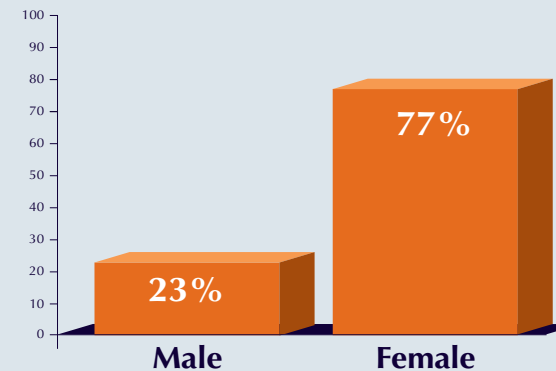
## Keppra (levetiracetam)



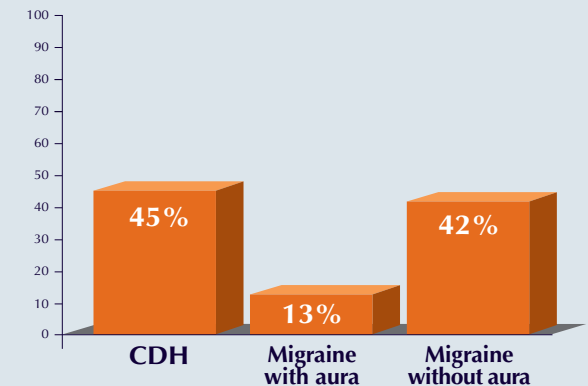
## Typical Headache Case

- 38 y.o. unemployed mother of two
- Severe headaches since age 12, initially seen in 1991. DX: Migraine without aura and episodic tension type headache
- Initially did well on amitriptyline until 1995
- Increase to 3-5/wk scale 10/10 with nausea and vomiting
- Throbbing diffuse headache aggravated by smells and noise
- Meds: Diltiazem, Verapamil, Topamax: minimal response to 2001; refused BOTOX® (dental surgery)
- Normal neuro exam, CCT, MRI
- July 2001 Rx Initiated with Keppra: 250 mg bid; increased 250mg q 5 days to 3000 mg/d in two divided doses
- **ONE headache July, NONE August**
- Current meds include:
  - Keppra 1500mg b.i.d.
  - Imitrex 100mg prn
  - Synthroid 0.15mg daily

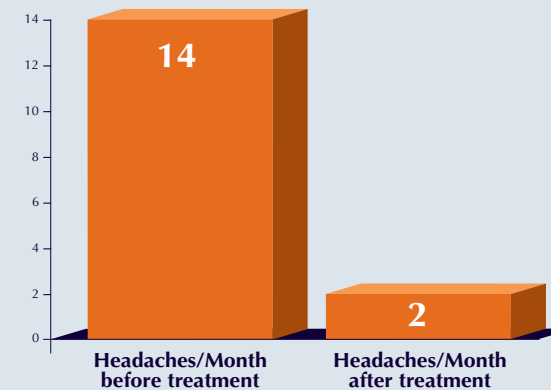
## Gender



## Headache Type



## Reduction in Headache Frequency



## Headache Improvement Scale

- 1 = NO improvement
- 2 = MILD improvement
- 3 = MODERATE improvement
- 4 = GOOD improvement
- 5 = EXCELLENT improvement

## CONCLUSIONS

- Keppra is an effective, safe drug for the management of patients with chronic migraine
- A slow titration regimen significantly improves tolerability
- 70% of patients with chronic daily headache (chronic migraine) experience improvement with Keppra