OHDSI Flash Study: Keppra and Angioedema

Jon Duke, MD MS
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OHDSI Mission

To improve health, by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.
We support this mission in many ways
When duty calls...
OHDSI will answer
### Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS) between October - December 2015

<table>
<thead>
<tr>
<th>Product Name: Active Ingredient (Trade) or Product Class</th>
<th>Potential Signal of a Serious Risk / New Safety Information</th>
<th>Additional Information (as of March 31, 2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keppra (levetiracetam) tablet, oral solution, injection</td>
<td>Angioedema</td>
<td>FDA is evaluating the need for regulatory action.</td>
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</tbody>
</table>
KEPPRA is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy.

KEPPRA is indicated as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy.

KEPPRA is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.
Angioedema
Angioedema

• Swelling of deep layers of skin (dermis, subcutaneous tissue, mucosa, submucosa)
• Commonly around lips or eyes
• May be hereditary or allergic reaction, often due to drugs
• Most famously associated with ACE-inhibitors
  – Incidence 0.1 - 0.7%
Proposed Study

• Retrospective new-user cohort study comparing levetiracetam vs phenytoin exposure and risk of angioedema
• Use propensity scoring to match treatment and comparator cohorts. Covariates will also be included in the outcome models.
• A set of 100 negative controls has been generated (using LAERTES and clinical review) to evaluate residual bias and compute calibrated p-values.
Optional Feasibility Scan with Calypso
Study R Package

• CohortMethod-based R package on GitHub
• Code will be tested and ready in ~1 week
• We will notify via forums when ready
Protocol

• Full protocol is available on the wiki
  – For those institutions requiring IRB for de-identified studies, the protocol can serve as basis
Result Dissemination

• While publication is an objective of every OHDSI study, we are also interested in the rapid dissemination of results to the community (including FDA)
• Would like to discuss people’s thoughts about posting results to OHDSI website for small, targeted studies
Thanks!

forums.ohdsi.org
github.com/ohdsi/community