Ziprasidone (Geodon®) in EMS
Geodon (ziprasidone)

- Unable to obtain any droperidol or haloperidol at this time.

- Due to concerns for the safety of our responders and our patients, we needed to find an acceptable substitute.
What is unknown- very few studies have looked at the use of chemical restraint agents in the pre-hospital setting.
Chemical Restraint in EMS Options with current Medication Shortages

JON JUI MD, MPH
Multnomah County EMS Chemical Restraint Protocol

Patient Restraint Flow Chart

Identify a patient posing a risk to self or others

Attempt to solicit cooperation by verbal means

Apply physical restraints if needed to ensure patient & responder safety

Consider cause of agitation

Psychiatric disorder OR Unknown causes

2.5 mg droperidol IV or 5 mg IM
After 10 min, repeat if needed
After 10 min, 2.5-5 mg midazolam IV or 2 mg IM
After 10 min, repeat if needed
Contact OLMC if needed for further instructions

Alcohol/drug intoxication or withdrawal OR Postural

2.5-5 mg midazolam IV or 5 mg IM
After 10 min, repeat if needed
After 10 min, 2.5 mg droperidol IV or 5 mg IM
After 10 min, repeat if needed
Contact OLMC if needed for further instructions
Geodon (ziprasidone)

- When rapid control of acute agitation is necessary to prevent harm to patient or staff
Geodon: Examples of Patient Presentations

- Found running naked and manic through street. Pt stabbed himself multiple times, restrained by police.
- Smoking crack, raging mad, hit bus station employee, yelling obscenities
- Broke out basement windows, trying to escape from aliens
- Patient screaming and yelling at police telling EMS to arrest police since they violated CIA law.
- Neighbor call PPD pounding on door. Patient in chicken coop stating snipers out to get him.
Geodon (ziprasidone)

- Fifth atypical antipsychotic medication to gain FDA approval in 2001.
- We have been using it in emergency departments safely for over 10 years.
Geodon (ziprasidone): Packaging

A: Geodon for injection is available as single dose vial 20 mg/mL.
Geodon (ziprasidone) :
Cost

- Geodon is approximately $20.00 per dose compared to $4.00 for droperidol.
Geodon in EMS

Results of 1st Two months deployment
Geodon in EMS

► From August 13, 2012 to October 25, 2012
► 32 Consecutive cases
Geodon: Patient Ages

Histogram

Mean = 38.81
Std. Dev. = 14.772
N = 32

Frequency

Age

10 20 40 60 80 100
## Geodon in EMS Demographics

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Females</td>
<td>11</td>
<td>35%</td>
</tr>
<tr>
<td>Males</td>
<td>21</td>
<td>65%</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>100%</td>
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# Geodon: Scene Indications

<table>
<thead>
<tr>
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<th>Yes</th>
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<tbody>
<tr>
<td>Danger Self</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td>Danger Others</td>
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<td>29</td>
</tr>
<tr>
<td>LE Present</td>
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<td>23</td>
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<tr>
<td>Condition</td>
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</tr>
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<td>--------------------</td>
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<td>------</td>
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<tr>
<td>ETOH</td>
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<td>0</td>
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<tr>
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<td>32</td>
<td>0</td>
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<tr>
<td>Psych</td>
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<td>16</td>
</tr>
<tr>
<td>Seizure</td>
<td>31</td>
<td>1</td>
</tr>
<tr>
<td>Head Injury</td>
<td>31</td>
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Geodon
Efficacy
A: The most likely earliest onset of the sedation effects of Geodon is approximately 15-20 minutes.

In most cases, the agitation will be markedly decreased in 30 to 45 minutes.
Behavioral Activity Rating Scale

1 = difficult or unable to rouse
2 = asleep but responds normally to verbal or physical contact
3 = drowsy, appears sedated
4 = quiet and awake (normal level of activity)
5 = signs of overt (physical or verbal) activity, calms down with instructions
6 = extremely or continuously active, not requiring restraint
7 = violent, requires restraint
Geodon (ziprasidone)

Slide 9
BARS Scores in PES Patients After Ziprasidone IM 20 mg

- Ziprasidone 20-mg IM (n=110)
- Conventional IM agents (n=9)
- Clinical trial of 20-mg IM Ziprasidone (n=41)

* P<.01 versus baseline for ziprasidone in PES patients.
† P<.01 versus baseline for conventional in PES patients.
BARS=Barnes-Akathisia Rating Scale; PES=psychiatric emergency services; IM=intramuscular.
Geodon (ziprasidone)

Slide 10

BARS Scores in PES Patients By Diagnosis After Ziprasidone IM 20 mg

* P<.05 for all PES groups versus baseline at 15 minutes.
† P<.01 for all PES groups versus baseline at 30 minutes and 2 hours.
Geodon (ziprasidone)

Slide 11
Effect of Ziprasidone Versus Droperidol and Midazolam on Agitation in the Medical ED

Agitated Patients versus Time

Time After Drug (min)

ED = emergency department; min = minutes.
# Geodon: Efficacy of Sedation

<table>
<thead>
<tr>
<th>Effect</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect None</td>
<td>0 %</td>
</tr>
<tr>
<td>Effect Minimal</td>
<td>12 (46%)</td>
</tr>
<tr>
<td>Effect Complete</td>
<td>13 (40%)</td>
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</tbody>
</table>
Geodon: Time to Effect Observed

Histogram

- Mean = 16.52
- Std. Dev. = 8.136
- N = 31
Geodon
Adverse Effects
Geodon (ziprasidone) vs Haldol QT Prolongation

Slide 8

Ziprasidone IM 20-mg Versus Haloperidol IM 7.5-mg: Effect on QTc at Cmax

Mean QTc Change, ms (95% CI)

- Injection 1
  - Zip 20 mg: 4.5 ms
  - Hal 7.5 mg: 6.0 ms

- Injection 2
  - Zip 30 mg: 12.8 ms
  - Hal 10 mg: 14.7 ms

Δ QTc Average Over 24 Hours

- Zip 3.4 ms
- Hal 6.3 ms

IM = intramuscular; Zip = ziprasidone; Hal = haloperidol.

Geodon (ziprasidone)
Side Effects

- Sedation,
- Hypotension
- Extrapyramidal symptoms (EPS)
Geodon (ziprasidone)

- prolongs QT and cause Torsades
Geodon Summary
Geodon: Summary

- Geodon was effective in decreasing agitation in approximately 50% of the patients.
- Onset of effect was approximately 15-20 minutes.
- No adverse effects were identified.
- Most likely the remainder of the effect was observed in the ED (work in progress).
The END