Sedation of the Agitated Poisoned Patient

...Is dexmedetomidine a reasonable first line to propose

Geoff Isbister
Newcastle, Australia
Declarations

- Funding from NSW Health for research on sedating aggressive patients.
- Other funding from National Health and Medical Research Council
  - Program Grant (1055176).
  - NHMRC Senior Research Fellowship ID1061041
- NO FUNDING from *Phebra*
  - HOWEVER, *Phebra* named the higher concentration of Droperidol (5mg/ml) as DORM™
Dexmede…..

- I can’t say it
- I still can’t spell it
- Requires IV access …. ?
- Short-acting; requires an infusion…
  - I’m an ED doctor …. 
- Causes hypotension
  - …possibly a way to sedate patients?
Dexmedetomidine

- Poisoned patients:
  - Setting: Where are they mainly?
- First-line?
  - Intervention: To use first every time
- Duration of therapy
  - Median length of stay of poisoned patient is 16 hours
- Route of administration
  - Intravenous VS Intramuscular
- Severity of agitation
  - delirium...anxious...agitated...violent
Who are we sedating?

- Poisoned patients:
  - Pre-hospital
  - Emergency Department - MAJORITY
  - Intensive Care Unit – MINORITY
Who are we sedating?

- 47 yo female with baclofen overdose 36h ago, awake but delirious in ICU
- 62 yo male post-benzo OD with aspiration pneumonitis, intubated and delirious
- 52 yo male post-oxycodone OD with hypoxic brain injury; delirious
- 22 yo male with diazepam (300mg) and sertraline overdose with agitation
- 27 yo female with amphetamine intoxication and severe agitation
- 34 yo male with alcohol intoxication; swearing and threatening staff
Definition of Acute Behavioural Disturbance (ABD)

- ABD = Severe agitation or aggression
- Requiring *physical restraint* and *parenteral sedation*

Not amenable to:

- Verbal de-escalation
- Consented to oral or IV sedation
Reason for ABD in the Emergency Department

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol intoxication</td>
<td>70%</td>
</tr>
<tr>
<td>Deliberate Self-harm</td>
<td>40%</td>
</tr>
<tr>
<td>Drug-induced delirium</td>
<td>8%</td>
</tr>
<tr>
<td>Psychosis</td>
<td>5%</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
</tr>
</tbody>
</table>

![Breath Alcohol Distribution](chart)

Intoxicated Patients
Establish the setting… DORM cases
WHAT IS THE EVIDENCE FOR DEXMEDETOomidine
Evaluation of dexmedetomidine therapy for sedation in patients with toxicological events at an academic medical center

In Intensive Care


Conclusion: Common adverse effects of DEX were noted in this study. The requirement for vasopressor support during therapy warrants further investigation into the safety of DEX in poisoned patients. Larger, comparative studies need to be performed BEFORE THE USE OF DEX CAN BE ROUTINELY RECOMMENDED IN POISONED PATIENTS.
Methods

INCLUSION

- Intubated
- Toxicological Consult
- Administered Dexmedetomidine

22 patients of 299 = 7.4%

- SO very select/BIASED group of poisoned patients
- Richmond Agitation Sedation Score (RASS) documented every 6h (median)
Results

- Median duration of therapy: 44.5 hr (IQR: 77hr)
- RASS goal not attained in 7/22 (32%)
- Adverse effects:
  - 5/22
  - Change in HR or BP
- Use of vasopressors:
  - 4/22 after DEX
- Median LOS = 9 days (IQR 35)
- Deaths: 2/22

Long Duration

Poor Effectiveness

>20% adverse effects

Long Stayers with complications
Conclusion: Common adverse effects of DEX were noted in this study. The requirement for vasopressor support during therapy warrants further investigation into the safety of DEX in poisoned patients. Larger, comparative studies need to be performed BEFORE THE USE OF DEX CAN BE ROUTINELY RECOMMENDED IN POISONED PATIENTS.

...WHO ARE INTUBATED AND IN INTENSIVE CARE WITH COMPLICATIONS AFTER THE INITIAL 24H POST-OVERDOSE
Dexmedetomidine

Dexmedetomidine in the emergency department: assessing safety and effectiveness in difficult-to-sedate acute behavioural disturbance

Leonie Calver and Geoffrey K Isbister

Objectives To investigate the safety and effectiveness of dexmedetomidine for sedating patients in whom previous attempts at sedation in the emergency department have failed.

Not first-line
Dexmedetomidine

Dexmedetomidine for difficult-to-sedate patients with acute behavioural disturbance is not safe in the emergency department setting.
Case Reports

Novel Use of Dexmedetomidine for the Treatment of Anticholinergic Toxidrome

Ashley Walker • Andrew Delle Donne • Elizabeth Douglas • Kristine Spicer • Thomas Pluim

A cannabinoid-intoxicated child treated with dexmedetomidine: a case report

Flora Cipriani*, Aldo Mancino, Silvia Maria Pulitanò, Marco Piastra and Giorgio Conti
Dexmedetomidine not a good first line option for the standard poisoned patient with agitation...

SO WHAT THEN? ...

First line – Droperidol
Second/Third line – hard to sedate Intramuscular versus Intravenous Time and Duration
The DORM Project

1. Pre-DORM:
   - Historical control study
   - Is IM sedation faster and safer?

2. DORM ... the original planned study
   - RCT
   - Is droperidol or midazolam “better”?

3. Post-DORM ... Phase IV type study
   - Safety of droperidol?
   - Can we implement the findings of the study?
   - Other third-line agent?
The impact of a standardised intramuscular sedation protocol for acute behavioural disturbance in the emergency department

Leonie A Calver¹², Michael A Downes¹²⁻³, Colin B Page²⁴, Jenni L Bryant¹⁵ and Geoffrey K Isbister¹²

Is IM sedation faster and safer?

Additional sedation:
- Pre-DORM = 88%
- DORM = 47%

Safety:
- Similar adverse effects and injuries
Route of administration:

- Intramuscular was **FASTER** and **AS SAFE** as IV

- DEX for intravenous administration
Randomized Controlled Trial of Intramuscular Droperidol Versus Midazolam for Violence and Acute Behavioral Disturbance: The DORM Study

Ann Emerg Med 2010

Geoffrey K. Isbister, BSc, FACEM, MD, Leonie A. Calver, Colin B. Page, MBBS, FACEM, Barrie Stokes, MMath, Jenni L. Bryant, Michael A. Downes, MBChB, FACEM

- RCT to compare effectiveness and safety of two drugs for sedation of ABD.
  - Speed of onset and duration of action
  - Adverse effects

- 3 arms all Intramuscular
  - DROPERIDOL 10mg
  - MIDAZOLAM 10mg
  - DROPERIDOL 5mg + MIDAZOLAM 5mg
DORM controlled trial … Conclusions

- **Droperidol IMI 10mg:**
  - As rapid sedation – median 20min
  - Less additional sedation – 33% (vs. 62%)
  - Low adverse effects – 6% (vs. 24%)

- **DEX for intravenous administration**
  - ? Time to sedation; long duration
  - Additional sedation in 23 – 77%
  - Adverse effects: 23 – 46%
DORM II

The Safety and Effectiveness of Droperidol for Sedation of Acute Behavioral Disturbance in the Emergency Department

Leonie Calver; Colin B. Page, MBChB; Michael A. Downes, MBBS; Betty Chan, MBBS, PhD; Frances Kinnear, MBBS; Luke Wheatley, MBBS; David Spain, MBBS; Geoffrey Kennedy Isbister, MD, BSc*

- Cohort of 1403 patients
  - 1009 with an ECG
- Prospective observational study
DORM II … Conclusions

- **Droperidol IMI 10mg:**
  - Rapid sedation: 20min
    - 97% sedated in 120 min
  - Additional sedation – 31%
  - Adverse effects – 5%
  - 13/1009 (1.3%) abnormal QT; no TdP
- **DEX for intravenous administration**
  - 64% sedated (attained RASS goal)
  - Additional sedation in 23 – 77%
  - Adverse effects: 23 – 46%
Five patients were not sedated < 120min or required additional sedation within 1h.

- 4/5 given 200mg or less.

49 patients administered rescue ketamine

- Median dose of ketamine was 300mg (50 to 500mg).
- Median time to sedation post-ketamine = 20min

Adverse effects: 3 (6%)

- 2 vomiting
- 1 transient desaturation to 90% after ketamine that responded to oxygen.
Ketamine as Rescue Treatment for Difficult-to-Sedate Severe Acute Behavioral Disturbance in the Emergency Department

Geoffrey Kennedy Isbister, MD, FACEM*; Leonie A. Calver, PhD; Michael A. Downes, MBBS, FACEM; Colin B. Page, MBBS

- **Ketamine IMI 4-6mg/kg:**
  - Successful sedation: 90%
  - Adverse effects: 6%

- **DEX as third line agent**
  - Successful sedation: 38 – 68%
  - Additional sedation: 15% required intubation
  - Adverse effects: 46%
Conclusion

...Is dexmedetomidine a reasonable first line to propose for sedation of the poisoned patient?
Questions?

Acknowledgements:
Leonie Calver
DORM Investigators
  Michael Downes
  Colin Page
  Betty Chan
  David Spain
  Francis Kinnear
  Luke Wheatley
Clinical Toxicology Research Group
  Renai Kearney
ED Nursing and Medical Staff
NSW Health funding
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   - RCT
   - *Is droperidol or midazolam “better”?*

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   - *Safety of droperidol?*
   - Can we implement the findings of the study?
   - *Other third-line agent?*
The DORM study

“D” = droperidol

“OR” = or

“M” = midazolam

- RCT to compare effectiveness and safety of two drugs for sedation of ABD.
  - Speed of onset and duration of action
  - Adverse effects

- 3 arms all Intramuscular
  - DROPERIDOL 10mg
  - MIDAZOLAM 10mg
  - DROPERIDOL 5mg + MIDAZOLAM 5mg

Is IM sedation faster and safer?

Additional sedation:
- Pre-DORM = 88%
- DORM = 47%

Safety:
- Similar adverse effects and injuries
Route of administration:

- Intramuscular was FASTER and AS SAFE
- DEX for intravenous administration
Why?... We know IV acts quicker

- **Strict guidelines** (inclusion/exclusion criteria)
- **Nurse initiated treatment**
- **Sedation drugs** clearly defined:
  - SET Drug to be used (minimises decision making)
  - SET Dose (adequate safe dose)
  - SET Route (easier quicker access)
- **Observations and monitoring**:
  - Improved recording of vital signs and adverse effects
The DORM study

“D” = droperidol

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- RCT to compare effectiveness and safety of two drugs for sedation of ABD.
  - Speed of onset and duration of action
  - Adverse effects

- 3 arms all Intramuscular

  DROPERIDOL 10mg
  MIDAZOLAM 10mg
  DROPERIDOL 5mg + MIDAZOLAM 5mg

Methods

**Code Black**

**ABD:**
- **222**
- **123** Excluded
- **8 Missed**

**Excluded = 123**
- Successful verbal de-escalation: 54
- Agreed to oral or IV: 12
- Age <18y: 3
- Transferred: 8
- Absconded: 2
- Escort off premises: 8
- No sedation or physical restraint: 31
- Psychosis: 3
- Repeat: 1
- Developmental Delay: 1

**ABD**

- **91**

**Droperidol**
- 33

**Droperidol/Midazolam**
- 29

**Midazolam**
- 29
Results... primary outcome

Median time to “all clear”:
  – Similar for all 3 groups = droperidol was NO slower
Results... additional sedation

Droperidol  = 33%
Midazolam   = 62%
Combination = 41%
Results... secondary outcomes

<table>
<thead>
<tr>
<th></th>
<th>Droperidol</th>
<th>Drop/Midaz</th>
<th>Midazolam</th>
</tr>
</thead>
<tbody>
<tr>
<td>% sedated &lt; 20min</td>
<td>73 %</td>
<td>79%</td>
<td>52 %</td>
</tr>
<tr>
<td>Staff and patient injuries</td>
<td>2 (0)</td>
<td>2 (1)</td>
<td>0 (1)</td>
</tr>
<tr>
<td>% addition sedation</td>
<td>33 %</td>
<td>41%</td>
<td>62 %</td>
</tr>
<tr>
<td>% further security calls</td>
<td>6%</td>
<td>14%</td>
<td>21%</td>
</tr>
<tr>
<td>Adverse effects - drugs</td>
<td>6 %</td>
<td>7%</td>
<td>28 %</td>
</tr>
<tr>
<td>Abnormal QT</td>
<td>7%</td>
<td>14%</td>
<td>7%</td>
</tr>
</tbody>
</table>
Results… QT effects

Pre-existing AF in one patient and pre-existing RBBB in one patient; no cases of TdP
Results... Sedation scores

Droperidol

Midazolam

Droperidol/Midazolam
Conclusions ... DORM controlled trial

- **Droperidol IMI 10mg:**
  - As fast at sedation
  - Requires less additional sedation
  - Safe in a small study;
    - less over-sedation and no abnormal QT

- **Midazolam IMI 10mg:**
  - No more rapid than IM droperidol
  - Significantly increased adverse effects
  - Requires more additional sedation

- **Combination:**
  - No more rapid than single agents
  - Similar adverse effects to droperidol
  - Much deeper sedation - unconscious
Previous studies...Knott et al 2006

Titrated 5 to 20mg IV every 5 minutes of either drug

<table>
<thead>
<tr>
<th>IV titration study</th>
<th>Droperidol 5-20mg (10)</th>
<th>Midazolam 5-20mg (5)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% sedated &lt; 5min</td>
<td>17%</td>
<td>45%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>% sedated &lt; 10min</td>
<td>53%</td>
<td>55%</td>
<td>0.91</td>
</tr>
<tr>
<td>% requiring further sedation within 1 hour</td>
<td>10%</td>
<td>19%</td>
<td></td>
</tr>
<tr>
<td>Adverse effects</td>
<td>13%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Assisted ventilation/intubation</td>
<td>0%</td>
<td>4%</td>
<td></td>
</tr>
</tbody>
</table>
Previous studies...Martel et al 2005

<table>
<thead>
<tr>
<th>IM Study</th>
<th>Droperidol 5mg</th>
<th>Midazolam 5mg</th>
<th>Ziprasidone 20mg</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% sedated &lt; 15min</td>
<td>60%</td>
<td>67%</td>
<td>39%</td>
<td>0.01</td>
</tr>
<tr>
<td>% further sedation</td>
<td>10%</td>
<td>50%</td>
<td>20%</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Respiratory depression (SpO₂ &lt;90%; CO₂ &gt;10)</td>
<td>40%</td>
<td>50%</td>
<td>57%</td>
<td>0.26</td>
</tr>
<tr>
<td>Supplemental Oxygen</td>
<td>8%</td>
<td>21%</td>
<td>15%</td>
<td></td>
</tr>
</tbody>
</table>

Mainly alcohol intoxication, but 20% also with head injuries.
DORM II

The Safety and Effectiveness of Droperidol for Sedation of Acute Behavioral Disturbance in the Emergency Department

Leonie Calver; Colin B. Page, MBChB; Michael A. Downes, MBBS; Betty Chan, MBBS, PhD; Frances Kinnear, MBBS; Luke Wheatley, MBBS; David Spain, MBBS; Geoffrey Kennedy Isbister, MD, BSc*

Cohort

– Aug 2009 to March 2013
– 1403 patients from 6 EDs (Mater, POWH, PA, Prince Charles, Gold Coast, Cairns)
– 34 yrs (IQR 25 to 43 years); 622 males (63%)
Study flow…

Estimated missed cases (213)  
(5 hospitals)  
No ABD chart  
Not given droperidol

Estimated Total ABD admissions  
1994

Exclusions (378)  
No ABD chart  
Not given droperidol

All recorded ABD admissions  
1781

No ECG (312)  
No ECG done  
ECG > 120min after dose

ABD admissions given droperidol  
with sedation scores  
1403

Effectiveness analysis  
Adverse Effects  
Torsades de Pointes

Repeat ECGs (82)  
> 1 ECG per admission  
Repeat admissions

ABD admission with an ECG  
within 120min of droperidol  
1091

ECG Safety Analysis

ABD admissions: one ECG per patient  
1009
Results... ECG group

- 1009 patients with an ECG within 2h of droperidol
  - median dose of 10mg (IQR:10-17.5mg).
  - 13/1009 patients had an abnormal QT (1.3%; 95% CI: 0.7 to 2.3%),
  - 7 had another cause attributed for prolonged QT
    - Methadone
    - Escitalopram
    - Amiodarone
    - Pre-existing
QT Nomogram

○ pre-existing
■ methadone
□ escitalopram
Δ amiodarone

Heart Rate (bpm)

QT (msec)
Results… sedation group

1403 patients sedated:
- median total droperidol dose = 10mg (IQR:10-20mg)
- median time to sedation = 20min (IQR:10-30min)
- sedated < 120min = 97%

- Additional sedation:
  - 435 (31%; 95%CI:28.6%-33.5%).

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desaturation (&lt;90%)</td>
<td>22*</td>
<td>1.6</td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>8</td>
<td>0.6</td>
</tr>
<tr>
<td>Hypotension</td>
<td>28</td>
<td>2.0</td>
</tr>
<tr>
<td>Extrapyramidal adverse events</td>
<td>7</td>
<td>0.5</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>Hypoventilation (respiratory rate &lt;12 breaths/min)</td>
<td>4</td>
<td>0.2</td>
</tr>
<tr>
<td>Seizure</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>No adverse events</td>
<td>1,333</td>
<td>95</td>
</tr>
</tbody>
</table>

*One patient had both airway obstruction and desaturation.
Current sedation regimen..

10 mg droperidol IM

69%

Sedated

Need more (15 min)?

10 mg droperidol IM / IV

Sedated

‘Difficult to sedate’ (3%)
Plan B…

‘Difficult to sedate’ (3%)

Potential options ??

Intravenous benzodiazepines
Ketamine as Rescue Treatment for Difficult-to-Sedate Severe Acute Behavioral Disturbance in the Emergency Department

Geoffrey Kennedy Isbister, MD, FACEM*; Leonie A. Calver, PhD; Michael A. Downes, MBBS, FACEM; Colin B. Page, MBBS

<table>
<thead>
<tr>
<th>Demographics/Characteristics</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (IQR), y</td>
<td>37 (20–82)</td>
<td></td>
</tr>
<tr>
<td>Male patient (%)</td>
<td>28</td>
<td>57</td>
</tr>
<tr>
<td><strong>Reason for presentation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deliberate self-poisoning*</td>
<td>16</td>
<td>33</td>
</tr>
<tr>
<td>Psychosis</td>
<td>14</td>
<td>29</td>
</tr>
<tr>
<td>Intoxicated</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Psychostimulants</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>Medical cause</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Dementia</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Brought in by police</td>
<td>20</td>
<td>41</td>
</tr>
<tr>
<td><strong>Sedation before ketamine (mg)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Droperidol (10)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Droperidol (10 × 2)</td>
<td>33</td>
<td>67</td>
</tr>
<tr>
<td>Droperidol (10 × 3)</td>
<td>11</td>
<td>22</td>
</tr>
<tr>
<td>Droperidol (25)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Droperidol (30) + midazolam (75)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Droperidol (20) + diazepam (10) + midazolam (10)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Midazolam (15)</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
Ketamine

49 patients administered rescue ketamine
- Median dose of ketamine was 300mg (50 to 500mg).
- Median time to sedation post-ketamine = 20min

Five patients were not sedated < 120min or required additional sedation within 1h.
4/5 given 200mg or less.

Adverse effects: 3 (6%)
- 2 vomiting
- 1 transient desaturation to 90% after ketamine that responded to oxygen.

Severe ABD requiring rescue sedation (Ketamine given)
- 49 (1.5%)

Successful sedation
- 44

No adverse effects
- 41
Ketamine

- Ketamine appeared effective and did not cause obvious harm in this small sample
- Potential option for patients who have failed previous sedation.
- A dose of 4-5mg/kg is suggested
- Doses <200mg are associated with treatment failure.
Ketamine

PAIN MANAGEMENT AND SEDATION/EDITORIAL

Let’s “Take ’Em Down” With a Ketamine Blow Dart

Steven M. Green, MD*; Gary Andolfatto, MD

<table>
<thead>
<tr>
<th>Report</th>
<th>Patients</th>
<th>Efficacy</th>
<th>Serious Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001 Roberts</td>
<td>1 ED adult</td>
<td>Effective</td>
<td>None</td>
</tr>
<tr>
<td>2004 Porter</td>
<td>2 out-of-hospital adults</td>
<td>Apparently effective</td>
<td>None</td>
</tr>
<tr>
<td>2005 Hick</td>
<td>1 out-of-hospital adult</td>
<td>Effective</td>
<td>None</td>
</tr>
<tr>
<td>2007 Melamed</td>
<td>5 out-of-hospital adults</td>
<td>Effective</td>
<td>None</td>
</tr>
<tr>
<td>2007 Svenson</td>
<td>4 out-of-hospital adults</td>
<td>Apparently effective</td>
<td>None</td>
</tr>
<tr>
<td>2012 Burnett</td>
<td>13 out-of-hospital adults</td>
<td>Apparently effective</td>
<td>3 hypoxia, 1 recurrent laryngospasm leading to intubation, 1 hypersalivation, 3 “emergence reactions”</td>
</tr>
<tr>
<td>2012 Le Cong</td>
<td>19 out-of-hospital adults</td>
<td>Effective</td>
<td>None</td>
</tr>
<tr>
<td>2013 Ho</td>
<td>2 out-of-hospital adults</td>
<td>Effective</td>
<td>None</td>
</tr>
<tr>
<td>2014 Pritchard</td>
<td>1 out-of-hospital adult</td>
<td>Effective</td>
<td>None</td>
</tr>
<tr>
<td>2014 Scheppke</td>
<td>52 out-of-hospital adults</td>
<td>50 of 52 sedated</td>
<td>3 “significant respiratory depression.” 2 treated with intubation and 1 with assisted ventilation</td>
</tr>
<tr>
<td>2015 Burnett</td>
<td>51 out-of-hospital adults</td>
<td>Apparently effective</td>
<td>14 intubations, but believed unrelated to ketamine</td>
</tr>
<tr>
<td>2015 Hopper</td>
<td>3 ED children and 29 ED adults</td>
<td>20 of 32 required additional sedatives</td>
<td>None</td>
</tr>
<tr>
<td>2015 Keseg</td>
<td>35 out-of-hospital adults</td>
<td>32 of 35 sedated</td>
<td>8 intubations, but believed unrelated to ketamine</td>
</tr>
<tr>
<td>2016 Kowalski</td>
<td>5 ED adolescents</td>
<td>Effective</td>
<td>None</td>
</tr>
<tr>
<td>2016 Isbister</td>
<td>49 out-of-hospital adults</td>
<td>44 of 49 sedated</td>
<td>None</td>
</tr>
</tbody>
</table>
Structured IM Sedation Protocol

1. **IM injection of the DORM study drug:**
   - DORM drug was labelled and kept in the ED

2. **Standard monitoring:**
   - defined monitoring of vital signs over 6 hours

3. **Sedation score:**
   - introduction and use of a sedation score as part of the standard observations for the patient

4. **Adverse effects and further sedation:**
   - recording of further sedation, adverse events, staff or patient injury for all patients.