Do All Penile Fractures Need Correction?

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Outline

• Xiaflex and the IMPRESS Trials
• Xiaflex at Walter Reed
  – Patient Demographics
  – Outcomes
  – Penile Fractures
• Discussion
  – Conservative vs. surgical management of Xiaflex-related penile fractures
Background

- Xiaflex (collagenase clostridium histolyticum)
  - Typically up to 4 cycles every 6 weeks of 2 injections given 24-72 hours apart
- IMPRESS Trials
  - 551 men received Xiaflex vs. 281 men received placebo
  - Maximum of 4 treatment cycles

- Average 17° improvement in curvature
- Adverse Events
  - Treatment group: 84.2% adverse events
  - Placebo arm: 36.3% adverse events
- Penile fractures (0.54%)
  - Linked to sexual intercourse
  - Managed surgically
Xiaflex at Walter Reed from JUN14-JUN16

Patient Demographics

- 27 patients
- 11 patients (40.74%) received more than 4 cycles

Presenting Symptoms

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Curvature</td>
<td>27/27</td>
<td>(100%)</td>
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<tr>
<td>Palpable plaque</td>
<td>12/27</td>
<td>(44.44%)</td>
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<tr>
<td>Erectile Dysfunction</td>
<td>9/27</td>
<td>(33.33%)</td>
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<td>Pain</td>
<td>6/27</td>
<td>(22.22%)</td>
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<tr>
<td>Hourglass deformity</td>
<td>5/27</td>
<td>(18.52%)</td>
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<td>Loss of length</td>
<td>2/27</td>
<td>(7.41%)</td>
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<tr>
<td><strong>Age, median (IQR)</strong></td>
<td>64 years (54, 64)</td>
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<tr>
<td><strong>Degrees of Curvature, median (IGR)</strong></td>
<td>42.5° (30, 45)</td>
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<tr>
<td><strong>Calcified plaque</strong></td>
<td>7/27 (25.93%)</td>
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<tr>
<td><strong>Duration of symptoms, median (IQR)</strong></td>
<td>4 years (2.5,7)</td>
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</tbody>
</table>
Outcomes

- Curvature improved: 82.35% (14/17)
  - Median: 22.5° improvement
  - IQR: 20, 30

- Decreased plaque size: 64.71%

- Increase in penile length: 35.29%

- Adverse events (AE) in 21/27 (77.78%)
  - Ecchymosis most common AE; in 17/27 (62.96%)
  - Pain and edema were less common
    - Pain in 11/27 (40.74%)
    - Edema in 7/27 (25.93%)
  - Atraumatic penile fractures in 3/27 (11.11%)
    - Not associated with sexual activity or other trauma
Patient 1

- 35 year old male with 30° curvature
- Completed 3 cycles
- 2 days after injection, developed nocturnal erection associated with pain, edema and worsening ecchymosis
- U/S inconclusive, MRI revealed penile fracture
- Underwent surgical repair
- Currently with stable curvature and normal erectile function
Patient 2

• 56 year old male with 45° curvature
• Completed 6 cycles
• 4 days after injection had nocturnal erection, subsequently noted ecchymosis, edema, and pain
• MRI revealed penile fracture
• Managed non-operatively
• Currently with improved curvature, normal erectile function
Patient 3

- 54 year old male with $20^0$ curvature
- Completed 3 cycles
- Presented with acute pain, edema, and ecchymosis 6 hrs after injection
- MRI revealed 1cm rupture
- Underwent surgical repair
- Currently with stable curvature and normal erectile function
Controversies in Management

• Standard penile fractures are typically diagnosed clinically without confirmatory imaging and repaired surgically

• Immediate surgery preferred

• Conservative management associated with more complications:
  – ED
  – Penile curvature
  – Pain with erections
Controversies in Management

Standard traumatic penile fractures
- Trauma to erect penis (usually misthrust during intercourse)
- Classic symptoms: snapping noise, pain, rapid detumescence, eggplant penis
- Larger tunical defect
- Injury to healthy, normal tissue

Xiaflex-related penile fractures
- Can be atraumatic
- Physical exam findings can be more subtle
- Smaller defects in the tunica
- Rupture through abnormal plaque tissue
- Surrounding tissues poor quality, friable
Controversies in Management

• Survey of SMSNA members performing Xiaflex injections:
  – 34% had patients with fractures
  – 67% managed ruptures surgically
    • 62% reported poorer tissue quality compared to standard fracture
  – No difference in outcomes

• If suspect penile fracture in Xiaflex patient:
  – Study with imaging
  – Consider non-operative management if small corporal rupture
| Patient 1 | 35 y/o, 30° curvature, 3 cycles | Pain, detumescence, ecchymosis after nocturnal erection | Surgical repair | Normal erectile function, stable curvature |
| Patient 2 | 56 y/o, 45° curvature, 6 cycles | Spontaneous erection, subsequent discomfort, pain, ecchymosis | Conservative management | Normal erectile function, improved curvature |
| Patient 3 | 54 y/o, 20° curvature, 3 cycles | Significant ecchymosis and edema hours after injection | Surgical repair | Normal erectile function, stable curvature |
Summary

• Higher penile fracture rate than reported in clinical trials
• Unique AE of atraumatic penile fractures
• Small tunical ruptures secondary to Xiaflex can be considered for nonoperative management
THANK YOU