Prospective study comparing a risk-based injection regimen versus an empiric approach to intracavernosal injection therapy

Introduction

• Employing ICI in practice is largely empirical, and has not been validated with evidence-based approaches
• We sought to evaluate if an algorithm that incorporates ED risk factors can help with initial agent ICI choice and dose selection
Objectives

• To compare two strategies for ICI to determine whether a risk-based approach is more efficacious, increases satisfaction and/or results in fewer treatment complications than an empiric approach.

• Primary outcome measure:
  – Difference in EDITS (Erectile Dysfunction Inventory and Treatment Satisfaction) at 3 and/or 6 months

• Secondary outcome measures:
  – Differences in IIEF-EF, SQoL or QEQ at 3 or 6 months
  – Complication rates
Methods

- A prospective IRB-approved database of patients enrolled in the ICI program at the Johns Hopkins Hospital from May 2012-2014 was amassed.
- Baseline demographic information, treatment outcomes and subjective patient evaluations of sexual function (IIEF, QEQ, SQoL and EDITS questionnaires) were obtained and analyzed at baseline, and at 3 and 6 months.
- Two approaches were compared: an empiric approach (group 1) vs. a risk-based approach (group 2)
- Dose titration was permitted in both groups.
- Statistical analysis was carried out using t-test, ANOVA and chi-squared analysis.
**Results - Demographics**

- 175 patients were enrolled with 3 and 6 month f/u at 57% and 35% respectively.

<table>
<thead>
<tr>
<th>Baseline Demographics</th>
<th>Group 1 – Empiric (SE)</th>
<th>Group 2 - Risk-Based (SE)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Men</td>
<td>57</td>
<td>118</td>
<td></td>
</tr>
<tr>
<td>% post prostatectomy</td>
<td>54.4</td>
<td>74.6</td>
<td></td>
</tr>
<tr>
<td>Mean Age</td>
<td>61.9 (1.4)</td>
<td>61.3 (0.7)</td>
<td>0.66</td>
</tr>
<tr>
<td>Mean QEQ</td>
<td>14.2 (3.5)</td>
<td>7.2 (1.8)</td>
<td>0.08</td>
</tr>
<tr>
<td>Mean SQoL</td>
<td>37.3 (3.3)</td>
<td>39.2 (2.2)</td>
<td>0.65</td>
</tr>
<tr>
<td>Mean IIEF-EF</td>
<td>8.1 (0.9)</td>
<td>7.0 (0.6)</td>
<td>0.30</td>
</tr>
</tbody>
</table>
Primary Outcome EDITS

Erectile Dysfunction Inventory of Treatment Satisfaction

No difference in treatment satisfaction between groups.

- Group 1 (Empiric)
- Group 2 (Risk-based)
Results

IIEF-Erectile Function Domain

Baseline 3 months 6 months

Group 1 (Empiric) Group 2 (Risk-based)
Results

Quality of Erections Questionnaire

- Baseline
- 3 months
- 6 months

Group 1 (Empiric)  Group 2 (Risk-based)
Results

Sexual Quality of Life Questionnaire

Baseline 3 months 6 months

Group 1 (Empiric) Group 2 (Risk-based)
## Results – D/C Tx and Medication switches

Table 2. Failure and Medication Switch Rate

<table>
<thead>
<tr>
<th></th>
<th>3 month</th>
<th></th>
<th>6 month</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td><strong>Group 1</strong> Failure rate</td>
<td>12</td>
<td>40%</td>
<td>8</td>
<td>40%</td>
</tr>
<tr>
<td>Switch rate</td>
<td>6</td>
<td>20%</td>
<td>4</td>
<td>20%</td>
</tr>
<tr>
<td><strong>Group 2</strong> Failure rate</td>
<td>25</td>
<td>37%</td>
<td>11</td>
<td>28%</td>
</tr>
<tr>
<td>Switch rate</td>
<td>14</td>
<td>21%</td>
<td>5</td>
<td>13%</td>
</tr>
</tbody>
</table>
## Priapism and Penile Pain

<table>
<thead>
<tr>
<th>Complications</th>
<th>Baseline (%)</th>
<th>3 months (%)</th>
<th>6 months (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priapism Group 1</td>
<td>0/57 (0)</td>
<td>1/30 (3.3)</td>
<td>1/20 (5)</td>
</tr>
<tr>
<td>Priapism Group 2</td>
<td>4/118 (3.4)</td>
<td>7/68 (10.8)</td>
<td>0/39 (0)</td>
</tr>
<tr>
<td>Penile Pain Group 1</td>
<td>-</td>
<td>1/30 (3.3)</td>
<td>2/20 (10)</td>
</tr>
<tr>
<td>Penile Pain Group 2</td>
<td>-</td>
<td>8/68 (11.8)</td>
<td>2/39 (5.1)</td>
</tr>
</tbody>
</table>

- There was a slightly higher rate of priapism complications at 3 months though it did not reach statistical significance ($p = 0.06$) when using the risk-based approach.
Discussion

• While ICI therapy certainly improves quality of erections and sexual quality of life in both treated groups, patient subjective satisfaction with treatment was no different between the empiric approach and the risk-based approach.

• The EDITS survey is specifically designed to assess patient satisfaction with the treatment received and noted no differences at 3 or 6 months.

• An empiric approach may have a reduced risk of priapism complications.
Limitations

- Due to high degree of variability in subjective responses, study may be underpowered.
- Poor follow-up rates at 6 months may be due to the therapy working or due to dissatisfaction and failure which could bias our results.
Conclusion

• We compared a risk-based vs. empiric approach to ICI therapy and found overall satisfaction with treatment and quality of erections, complication and failure rates to be similar between both approaches.