This analysis examines differences in pain control and safety that may be related to differences in administration technique.

**Subjects**

There is a need for effective, non-opioid postoperative therapeutic options that provide pain relief through 72 hours and are easy to administer.

Local anesthetics only effectively address postoperative pain for 8-12 hours.

- **Figure 1** – Clinically significant renal or hepatic abnormalities (AST or ALT >3x ULN, creatinine >2x ULN)
- **Figure 2** – Administration by instillation is more convenient, less invasive, and potentially reduces the risk of procedural complications, such as venous puncture.
- **Figure 3A** – Short-term opioid use can also lead to long-term opioid dependency.
- **Figure 3B** – The percentage of opioid-free patients.
- **Figure 4** – The administration of HTX-011 by injection or instillation was associated with similar pain scores and opioid use outcomes.

**METHODS**

Local Administration of HTX-011, a Long-Acting Biochronomer®-Based Bupivacaine/Meloxicam Combination, in Hernia Repair Provides Similar Initial Results Whether Injected or Instilled

**Authors:** Harold S. Minkowitz,1 Peter Winkle,2 Erol Onel,3 Guy Boccia,3 Alice Chu,3 Neil J. Clendenin,3 Mary Rose Keller,3 Thomas Ottoboni,3 Sanjay S. Patel,3 & Barry Quart1

**Affiliations:**
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- 2Anaheim Regional Medical Center, Anaheim, CA
- 3Heron Therapeutics, Inc. San Diego, CA

**BACKGROUND**

- **Figure 1** – Description of patient demographics. Not Hispanic 8 (57) 10 (63) 19 (61)
- **Table 1** – Race, n (%) Caucasian 11 (79) 14 (88) 24 (77)
- **Table 2** – Sex, n (%) Male 13 (93) 16 (100) 30 (97)
- **Table 3** – Age, years Mean 43.6 44.9 44.8

**RESULTS**

**EFFICACY OF HTX-011 BY ADMINISTRATION TECHNIQUE**

<table>
<thead>
<tr>
<th></th>
<th>HTX-011B 400 mg by injection</th>
<th>HTX-011B 400 mg by instillation</th>
<th>Saline Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Opioid Consumption (mg)</strong></td>
<td>0.0 (0)</td>
<td>0.0 (0)</td>
<td>0.0 (0)</td>
</tr>
<tr>
<td><strong>Mean SPI0-24</strong></td>
<td>6.5 (N = 16)</td>
<td>6.5 (N = 16)</td>
<td>0.0 (N = 31)</td>
</tr>
</tbody>
</table>
| **Figure 3A** – Mean Summed Pain Intensity Scores Through 24 Hours (SPI0-24) Following Surgery. **Figure 4A** – Distribution of Pain Intensity Scores Through 24 Hours (SPI0-24) Following Surgery. **Figure 4B** – Distribution of Pain Intensity Scores Through 24 Hours (SPI0-24) Following Surgery.

**SAFETY OF HTX-011 BY ADMINISTRATION TECHNIQUE**

- **Figure 3A** – No clinically meaningful differences were observed in vital signs, laboratory tests, ECG findings, or wound assessment.

**CONCLUSIONS**

- **Figure 4A** – Treatment in both HTX-011B administration arms was similarly well tolerated.
- **Figure 4B** – The administration of HTX-011B by injection or instillation was associated with similar pain scores and opioid use outcomes.

**REFERENCES**

- **Clarke et al.**. *BMJ* 2016;157:1259-1265.
- **Marcaine [prescribing information].** Lake Forest, IL: Hospira, Inc; 2011.

**Acknowledgements**

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- This study was supported by Heron Therapeutics, Inc.
- Medical writing and editorial assistance were provided by ApotheCom (San Francisco, CA).

**Table 3 – Summary of Treatment Emergent Adverse Events (TEAEs)**

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<td>4 (25.0%)</td>
<td>16 (51.6%)</td>
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<tr>
<td><strong>Any TEAE</strong></td>
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<tr>
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- **Figure 4A** – The most common TEAEs were nausea, headache, and constipation.

**SAFETY OF HTX-011 BY ADMINISTRATION TECHNIQUE**

- **Figure 3A** – No deaths, treatment-related serious AEs, or AEs leading to early termination from the study were reported.
- **Figure 4A** – The most common TEAEs were nausea, headache, and constipation.

**Table 3 – Summary of Treatment Emergent Adverse Events (TEAEs)**

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