INTRODUCTION

• The most common pain after a surgery occurs within the first 72 hours.
• Adequate post-surgical pain management during this period is crucial to preventing adverse outcomes.
• The normal inflammatory process after acute injury (eg, surgical incision) creates an acidic environment that may amplify pain.
• Baseline is important for local analgesics used for post-surgical relief; prevents systemic formations including back pain.

METHODS

• The primary endpoint of the study was pain intensity at 72 hours.
• The secondary endpoint was overall pain at 24 hours.
• Pain was assessed using an 11-point (0, no pain-10, worst pain imaginable) numeric rating scale.
• After eligible subjects provided informed consent and underwent surgery, each was kept in the hospital for 72 hours.

RESULTS

Baseline Population Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bupivacaine ER 200 mg</th>
<th>Meloxicam ER 75 mg</th>
<th>HTX-011 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Intensity at 72 Hours</td>
<td>0 (n = 32)</td>
<td>0 (n = 31)</td>
<td>0 (n = 83)</td>
</tr>
</tbody>
</table>

SYNERGY

<table>
<thead>
<tr>
<th>Synergistic Combination</th>
<th>Bupivacaine ER 200 mg + Meloxicam ER 75 mg</th>
<th>HTX-011 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Intensity at 72 Hours</td>
<td>0 (n = 32)</td>
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EFFICACY

Postoperative Pain Relief

• HTX-011 provided significantly better pain relief than either bupivacaine HCl or saline placebo after bunionectomy.
• HTX-011 significantly reduced pain intensity through the first 72 hours after surgery compared with bupivacaine ER, bupivacaine HCl, or saline placebo.

Figure 1. Mean pain intensity through 72 hours after bunionectomy or herniorrhaphy (WOCF)a

• The mean bupivacaine plasma concentration after needle-free application of HTX-011 reached a Cmax of 271 ng/mL.
• The adverse event profile of HTX-011 was not clinically meaningfully different from the adverse event profile of bupivacaine or saline placebo.

Figure 4. Use of opioid medication through 72 hours

• HTX-011 reduced pain intensity through the first 72 hours after surgery compared with bupivacaine ER, bupivacaine HCl or saline placebo in both surgical models.

• The mean pain intensity at 72 hours for HTX-011 subjects was significantly lower than for bupivacaine HCl (25.09 MMEs, p = 0.3324) and saline placebo (28.94 MMEs, p = 0.0815) through 72 hours.

Figure 5. Mean pain intensity through 72 hours after bunionectomy or herniorrhaphy (WOCF)

CONCLUSIONS

• Across multiple surgical models, HTX-011 provided a synergistic analgesic effect that was greater than the sum of the individual components.
• HTX-011 reduced pain intensity through the first 72 hours after surgery compared with bupivacaine ER, bupivacaine HCl or saline placebo in both surgical models.
• The mean pain intensity at 72 hours for HTX-011 subjects was significantly lower than for bupivacaine HCl (25.09 MMEs, p = 0.3324) and saline placebo (28.94 MMEs, p = 0.0815) through 72 hours.

REFERENCES

2. Miller's Anesthesia
3. J Pain Symptom Manage

Presented at the 43rd Annual Regional Anesthesiology and acute Pain Medicine Meeting April 19-21, 2018, New York, NY