INTRODUCTION

- Early postoperative pain typically peaks within 24 hours after surgery and continues for a period of 72 hours.
- Complete postoperative pain management involving the use of opioids may be necessary after surgery.

SABER-R®-Bupivacaine Reduces Postoperative Pain Intensity and Opioid Use for 72 Hours in Soft-Tissue and Bony Surgeries

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OBJECTIVE

To evaluate the efficacy, safety, and doseresponse of SABER-Bupivacaine compared with SABER-placebo following soft-tissue and bony surgery.

METHODS

- Study Designs: 2 randomized, double-blinded, placebo-controlled trials enrolling patients undergoing either soft tissue (subcutaneous tissue) or inguinal hernia repair or bony (orthopaedic subchondral decompression [ASD]) surgery.
- Patient Characteristics and Baseline Demographics:

<table>
<thead>
<tr>
<th>Group</th>
<th>N (%)</th>
<th>Age, years, mean (SD)</th>
<th>Sex, n (%): Female/Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>SABER-Placebo (n = 24)</td>
<td>13 (54)</td>
<td>51.6 (10.7)</td>
<td>9 (37.5)/14 (58.3)</td>
</tr>
<tr>
<td>SABER-Bupivacaine (n = 53)</td>
<td>29 (62.3)</td>
<td>50.2 (9.9)</td>
<td>16 (30.2)/37 (71.4)</td>
</tr>
</tbody>
</table>

RESULTS

- Efficacy End Points
  - In patients undergoing inguinal hernia repair surgery, mean pain intensity was significantly lower in patients receiving SABER-Bupivacaine compared with those receiving placebo (Figure 1).
  - In patients undergoing ASD surgery, mean pain intensity was significantly lower in patients receiving SABER-Bupivacaine compared with those receiving placebo (Figure 2).

- Conclusions
  - SABER-R®-Bupivacaine significantly decreased mean pain intensity on movement compared with placebo for 72 hours after surgery in patients undergoing inguinal repair and ASD surgery.
  - In patients undergoing ASD surgery, SABER-R®-Bupivacaine also significantly reduced the use of rescue opioid medication compared with SABER-placebo for the first 72 hours after surgery with meaningful reduction on each day.
  - These results indicate that patients treated with SABER-R®-Bupivacaine experienced significantly less pain and required significantly less rescue medication during the first 72 hours compared with patients treated with SABER-placebo, regardless of surgery type.

- Discussion
  - SABER-R®-Bupivacaine may provide a simple-to-use foundation for reliable, continuous 72-hour pain relief in a variety of surgeries to help preserve opioid use and its corresponding adverse events.
  - SABER-R®-Bupivacaine has the potential to improve recovery and reduce readmissions and call-backs due to inadequate pain relief or opioid-related adverse events.

REFERENCES

5. John Moodie, MD, FRCPC, FRCA. DURECT Corp., Cupertino, CA. Department of Anesthesia, University of California, San Francisco, CA. Orthopedic Surgery Research Unit, Medical Education, Aalborg University Hospital, Aalborg, Denmark.

Figure 1. Pain intensity on movement in patients undergoing inguinal hernia repair surgery.

Figure 2. Pain intensity on movement in patients undergoing ASD surgery.

Figure 3. Morphine equivalent use by study day in patients undergoing inguinal hernia repair.

Figure 4. Morphine equivalent use by study day in patients undergoing ASD surgery.