

HTX-011 as the Foundation of a Non-Opioid, Multimodal Analgesic Regimen Reduces the Need for Opioids Following Herniorrhaphy in a Real-World Study

INTRODUCTION

- A median of 30 opioid pills are prescribed following herniorrhaphy^{1,2}
- HTX-011 is an extended-release dual-acting local anesthetic consisting of bupivacaine and low-dose meloxicam in a proprietary BiochronomerTM polymer (Heron Therapeutics, San Diego, CA)
- The superior pain reduction and opioid-sparing properties of HTX-011 in herniorrhaphy recovery have been demonstrated in a randomized, double-blind, phase 3 study (EPOCH-2, NCT03237481)³ and associated follow-on study (NCT03695367, Poster 4-413)⁴
- The following algorithm retrospectively identified patients who may need an opioid discharge prescription:
- Patients who receive an opioid or have a numeric rating scale (NRS) pain score of \geq 6 within the first 2 hours after surgery
- The Helping Opioid Prescription Elimination (HOPE) Project is the first step in demonstrating Heron's commitment to create real-world protocols that can reduce or eliminate the need for opioids after surgery

OBJECTIVES

- Investigate the use of HTX-011 as the foundation of an over-the-counter (OTC) multimodal analgesia (MMA) regimen to achieve complete opioid freedom after surgery
- Validate the proposed algorithm for identifying which patients require an opioid prescription at discharge in a real-world setting
- Identify which of two scheduled OTC MMA regimens, both using intraoperative HTX-011 as the foundation, results in fewer patients requiring an opioid prescription post-herniorrhaphy

METHODS

- This phase 3b open-label study enrolled patients scheduled to undergo open inguinal herniorrhaphy with mesh at 7 study centers across the United States
- All patients received:
- Oral ibuprofen 400 mg and oral acetaminophen 1 g prior to surgery
- Single intraoperative dose of HTX-011 300 mg/9 mg (bupivacaine/meloxicam) administered via needle-free application to the surgical site prior to wound closure at the end of surgery
- Scheduled non-opioid postoperative MMA regimen consisting of oral ibuprofen 600 mg and acetaminophen I g

John Fanikos,¹ Harold Minkowitz,² Michael Reinhorn,³ Barry Quart⁴

¹Brigham and Women's Hospital, Boston, MA, USA; ²HD Research, LLC, Houston, TX, USA; ⁴Heron Therapeutics, Inc., San Diego, CA, USA

- Patients were randomized into two cohorts (Figure I)
- Cohort I (Alternating MMA, n = 46) alternated taking ibuprofen and acetaminophen every 6 hours, so that one medication was taken every 3 hours while awake after surgery
- Cohort 2 (Concurrent MMA, n = 47) took ibuprofen and acetaminophen together, every 6 hours while awake after surgery



APAP, acetaminophen; IBU, ibuprofen; MMA, multimodal analgesia; NRS, numeric rating scale of pain intensity; q6h, every 6 hours. ^aWhile patient is awake.

RESULTS

Efficacy

- Results were similar between MMA cohorts (Figure 2)
- 95% of patients had an opioid-free recovery through Day 15
- 91% of patients were managed without an opioid prescription
- There were no callbacks to request additional analgesia by any patient discharged without an opioid prescription
- On average, patients were discharged between 2 and 3 hours following surgery with a mean NRS pain score of 2.6 (indicating only mild pain)



MMA, multimodal analgesia.





MMA, multimodal analgesia; SE, standard error; TSQM, treatment satisfaction questionnaire for medication.





SUMMARY AND CONCLUSIONS

- HTX-011 as the foundation of a scheduled, non-opioid OTC MMA regimen allowed 95% of patients to remain opioid-free following herniorrhaphy
- Alternating and concurrent ibuprofen/acetaminophen MMA regimens were equally effective with high patient satisfaction
- No serious adverse events were reported
- Providing a postoperative opioid prescription only for patients who received an opioid prior to discharge and/or had a NRS pain score ≥ 6 is an effective and practical algorithm
- There were no callbacks to request new opioid prescriptions
- HTX-011 with OTC MMA, in combination with an easy-to-use algorithm, was effective in a real-world environment and has the potential to dramatically reduce the number of opioids sent home with patients following herniorrhaphy (Table I)

Table I. Potential Impact of HOPE-I ^{2,5}			
	Pills Prescribed	Pills Consumed	Pills Leftover
Current practice estimates	24,000,000	7,200,000	16,800,000
HOPE-I estimates	774,194	283,871	490,323
Potential Reduction with HTX-011 + OTC MMA	23,225,806	6,916,129	16,309,677

MMA, multimodal analgesia; OTC, over-the-counter.

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