A SINGLE ADMINISTRATION OF DEPOBUPIVACAINE™ INTRAOPERATIVELY PROVIDES THREE-DAY ANALGESIA AND REDUCTION IN USE OF RESCUE OPIOIDS IN PATIENTS UNDERGOING HEMORRHOIDECTOMY.

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Purpose: This study evaluated the efficacy and safety of a single administration of liposomal extended-release bupivacaine (DB) compared with bupivacaine HCl with epinephrine (Bup/epi) in patients undergoing two- or three-column excisional hemorrhoidectomy.

Methods: Three doses of DB were compared with Bup/epi in a randomized, double-blind, parallel-group, dose-ranging study. During surgery, tissue surrounding the wound was infiltrated with DB 75mg (n=25), DB 225mg (n=25), DB 300mg (n=25) or Bup/epi 75mg (n=25). All subjects also received one dose of IV ketorolac 30mg and oral acetaminophen 1000mg three times daily through 96h. Rescue medication consisted of parenteral opioid followed by oral oxycodone. After surgery, the following outcomes were assessed: pain at rest, pain on first bowel movement (BM), and pain on all BMs within a calendar day; time to first opioid rescue; total opioid rescue; and fraction of subjects requiring opioid rescue.

Results: DB reduced pain on first BM and pain of all BMs within each calendar day dose-dependently by intensity and duration. All DB doses decreased pain at rest throughout the 4-day observation period. DB increased the fraction of subjects avoiding opioid rescue (16%, 20%, 32% for 75, 225, 300 mg, respectively) compared with Bup/epi (8%). DB 300mg significantly reduced opioid consumption by 59% and significantly increased the time to first opioid rescue compared with Bup/epi (19 vs 8h, respectively; $P<0.05$) and also decreased total opioid consumption vs Bup/epi (13 vs 33mg morphine equivalents, respectively). Postoperative nausea and vomiting (PONV) was not noted with the 300-mg DB dose, a significant improvement when compared with Bup/epi ($P=0.0349$). There were no serious adverse events (SAEs) attributable to DB. Wound healing was normal.

Conclusions: A single intraoperative administration of DB resulted in 3 days of analgesia in subjects undergoing hemorrhoidectomy, and was associated with decreased opioid use and a reduction in commonly associated side effects (ie, PONV). Wound healing was normal and there were no SAEs attributable to DB.