

EXPAREL™, an investigational extended-release liposome injection of bupivacaine, delays time to first opioid and reduces opioid requirements for three days after hemorrhoidectomy

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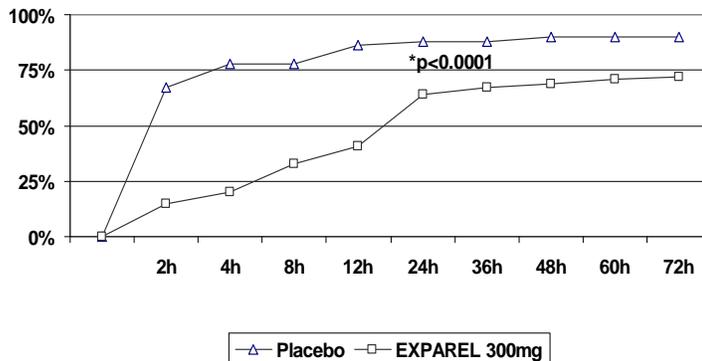
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Introduction: Liposomal drug-containing formulations can provide for controlled drug release over an extended period of time. This Phase 3 clinical trial compared EXPAREL, an experimental formulation of bupivacaine encapsulated in multivesicular liposomes, to placebo and studied opioid requirements as well as other secondary endpoints after hemorrhoidectomy procedures.

Materials/Methods: After obtaining IRB/IEC approval, 189 consecutive patients at 13 sites in Serbia, Poland, and Georgia were randomized to receive either a single injection of placebo or of 300mg EXPAREL at the conclusion of a Milligan-Morgan hemorrhoidectomy. Data collected included pain intensity scores via a numeric rating scale (NRS) for pain (0-10) and postoperative rescue Morphine used.

Results: More patients in the EXPAREL group than in the placebo group remained opioid-free (36.2% vs 11.8% through 24 hours, $p < 0.0001$; 27.7% vs 9.7% at 72 hours, $p = 0.0007$), despite having statistically significantly lower pain scores at every timepoint tested (Area Under the Curve of the NRS scores for pain from 0 through 72 hours: 142 vs 202; $p < 0.0001$). The total amount of opioids used was also statistically significantly lower through each timepoint through 72 hours. The median time to first opioid rescue in subjects who received placebo was 1 hour 10 minutes, compared with 14 hours 20 minutes in subjects who received EXPAREL ($p < 0.0001$; see figure 1 below).

Figure 1: Median time to first opioid rescue



Conclusions: EXPAREL, an investigational long-acting local analgesic, delayed time to first opioid and decreased opioid requirements for three days after hemorrhoidectomy. EXPAREL has the potential to offer clinically meaningful analgesia and decrease the need for opioid analgesic drugs after these procedures.