

Nicklaus Children's Hospital
MIAMI CHILDREN'S HEALTH SYSTEM
Heart Program

Liposomal Bupivacaine: A novel, long acting local anesthetic

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Abstract

Post-operative pain control continues to be a problem in surgical patients. A novel formulation of an ultra-long acting local anesthetic is now available in the US: Exparel or liposomal bupivacaine. Liposomal bupivacaine is made up of microscopic polyhedral particles. The liposomes encapsulate the drug, bupivacaine hydrochloride, without altering molecular structure. This provides the reliable low dose release of the bupivacaine over time, providing long-lasting, post-surgical pain relief over the course of 2-3 days. This eliminates the need for titration of a single dose or the need for external devices or pumps to prolong analgesia.

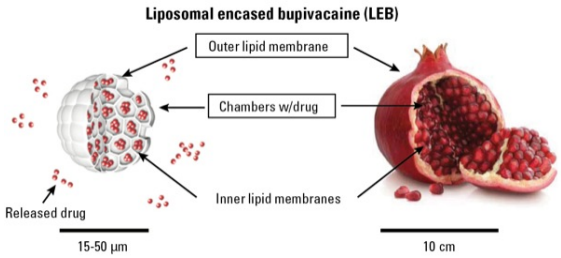
Plasma bupivacaine levels may persist for 96 hours after injection. Peak plasma concentrations are lower in magnitude and occur later in time than after a similar injection with bupivacaine HCl. Plasma bupivacaine concentrations are not correlated with local efficacy.

Safety profile was evaluated in 10 clinical trials in patients undergoing a variety of surgical procedures. Most common adverse events were nausea, constipation and vomiting. Exparel demonstrated a favorable cardiac profile. There was no cardiac toxicity and no QTc prolongation, even a supra-therapeutic doses. Rate of absorption is dependent on total dose administered, route of administration and vascularity of the surgical site.

Efficacy has been established. Multiple trials demonstrated a significant reduction if pain intensity scores and a reduction if overall opioid consumption compared to placebo.

Liposomal bupivacaine is a safe and effective novel drug to treat post-surgical pain.

Image



Recent Publications

1. Bramlett K, Onel E, Viscusi ER, Jones K. A randomized, double-blind, dose-ranging study comparing wound infiltration of DepoFoam bupivacaine, an extended-release liposomal bupivacaine, to bupivacaine HCl for postsurgical analgesia in total knee arthroplasty. *Knee*. 2012;19(5):530-536
2. Bergese SD, Onel E, Morren M, Morganroth J. Bupivacaine extended-release liposome injection exhibits a favorable cardiac safety profile. *Reg Anesth Pain Med*. 2012;37(2):145-151.
3. Naseem A, Harada T, Wang D, et al. Bupivacaine extended release liposome injection does not prolong QTc interval in a thorough QT/QTc study in healthy volunteers. *J Clin Pharmacol*. 2012;52(9):1441-1447.
4. Gorfine SR, Onel E, Patou G, Krivokapic ZV. Bupivacaine extended-release liposome injection for prolonged postsurgical analgesia in patients undergoing hemorrhoidectomy: a multicenter, randomized, double-blind, placebo-controlled trial. *Dis Colon Rectum*. 2011;54(12):1552-1559
5. Golf M, Daniels SE, Onel E. A phase 3, randomized, placebo-controlled trial of DepoFoam® bupivacaine (extended-release bupivacaine local analgesic) in bunionectomy. *Adv Ther*. 2011;28(9):776-788

Biography

Dr. Tirotta has been an active member of Nicklaus Children's Hospital medical staff since 1991, practicing with the Department of Anesthesiology; he has served as the Director of Cardiac Anesthesia since 2002. He has served as Chief of the Department of Anesthesia since July 2017. He also has a clinical appointment with the Department of Anesthesiology at The University of Miami School of Medicine

Dr. Tirotta received his BA from Cornell University in 1982 and his MD from New York University School of Medicine in 1986. He also received an MBA degree from Columbia University in 1999. Dr. Tirotta completed his internship in Internal Medicine at SUNY at Stony Brook in 1987. He completed his residency training in anesthesiology at the University of Miami/Jackson Memorial Hospital in 1990; he sub-specialized in pediatric and cardiovascular anesthesia, including heart transplantation.

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