

Administration Case Report: Arthroscopic Rotator Cuff Repair

NON-OPIOID
EXPAREL[®]
(bupivacaine liposome injectable suspension)

This case report represents the individual experience of Dr Jacob Hutchins, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing arthroscopic rotator cuff repair.

Pacira BioSciences, Inc. recognizes that there are alternative methodologies for administering local anesthetics, as well as individual patient considerations when selecting the dose for a specific procedure.

EXPAREL is a local anesthetic that produces postsurgical analgesia in patients aged 6 years and older. It is administered via single-dose infiltration. When infiltrated into the surgical site, it produces local analgesia. It may also be infiltrated in the fascial plane to produce regional analgesia as a regional field block. Regional anesthetic techniques to produce regional analgesia include, but are not limited to, transversus abdominis plane (TAP) block, pectoralis (PEC) and serratus anterior plane (SAP) blocks, erector spinae plane (ESP) block, and quadratus lumborum (QL) block. EXPAREL may also be administered as an interscalene brachial plexus nerve block in adults to produce postsurgical regional analgesia in total shoulder arthroplasty (TSA) and rotator cuff repair (RCR) procedures.

CASE INFORMATION

Physician Name	Jacob Hutchins, MD
Affiliation	University of Minnesota, Director of the Division of Regional Anesthesia, Acute Pain, and Ambulatory Anesthesia; Medical Director of Anesthesiology of the University of Minnesota Health Ambulatory Surgical Center
Nerve Block Performed	Interscalene brachial plexus nerve block
Inpatient or Outpatient Setting	Outpatient

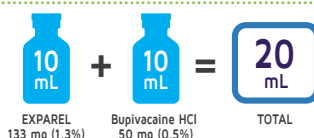
PATIENT CHARACTERISTICS

Gender	Female
Age	53 years
Patient History and Characteristics	Previous smoker, history of nephrolithiasis and a rotator cuff repair Scheduled for arthroscopic rotator cuff repair , subacromial decompression, distal clavicle resection, and biceps tenotomy Anesthetic plan: Ultrasound-guided interscalene brachial plexus nerve block anesthesia care

PROCEDURAL DETAILS

Preoperative Analgesics Used	PO acetaminophen 975 mg PO gabapentin 300 mg
Intraoperative Anesthetics Used	Low-dose propofol infusion Low-dose dexmedetomidine infusion IV ketamine 0.25 mg/kg
Nerve Block Performed	Interscalene brachial plexus nerve block with 10 mL (133 mg) EXPAREL admixed with 10 mL (50 mg) 0.5% bupivacaine HCl

Dose of EXPAREL and Total Volume Used



IV=intravenous; PO=by mouth.

The recommended dose of EXPAREL for adults is based on the size of the surgical site, the volume required to cover the area, and individual patient factors that may impact the safety of an amide local anesthetic. The maximum dose of EXPAREL should not exceed 266 mg. The recommended dose of EXPAREL for patients aged 6 to <17 years old is 4 mg/kg, up to a maximum of 266 mg. The maximum dose of EXPAREL for interscalene brachial plexus nerve block in adults should not exceed 133 mg.

EXPAREL can be administered unexpanded (20 mL) or expanded to increase volume up to a total of 300 mL (final concentration of 0.89 mg/mL [ie, 1:14 dilution by volume]) with normal (0.9%) saline or lactated Ringer's solution.

Bupivacaine HCl (which is approved for use in patients aged 12 and older) may be administered immediately before EXPAREL or admixed in the same syringe, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2. Admixing may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. The toxic effects of these drugs are additive and their administration should be used with caution, including monitoring for neurological and cardiovascular effects related to local anesthetic systemic toxicity. Other than with bupivacaine, EXPAREL should not be admixed with other drugs prior to administration.

Please see Important Safety Information on reverse and refer to accompanying full Prescribing Information, which is also available at www.EXPAREL.com.

DR HUTCHINS' INTERSCALENE BRACHIAL PLEXUS NERVE BLOCK TECHNIQUE

Dr Hutchins performed an interscalene brachial plexus nerve block using ultrasound guidance to ensure accuracy of infiltration. With the patient in a supine position, with the head of the bed elevated 45 degrees, a linear high-frequency 13-6 MHz probe was used to identify the interscalene brachial plexus between both the anterior and middle scalene muscles.

Step 1: A 21-gauge, 100-mm echogenic needle was inserted in the plane lateral to medial until the tip was just lateral to the bottom of the interscalene brachial plexus. Dr Hutchins deposited 10 mL of the admixture inside the compartment (see Needle path 1 in Figure).

Step 2: The needle was repositioned until it was just lateral to the top of the interscalene brachial plexus, where the remaining 10 mL of admixture was deposited. Nerve block was performed under direct visualization to ensure proper placement and adequate spread of EXPAREL® (bupivacaine liposome injectable suspension) admixture (see Needle path 2 in Figure).

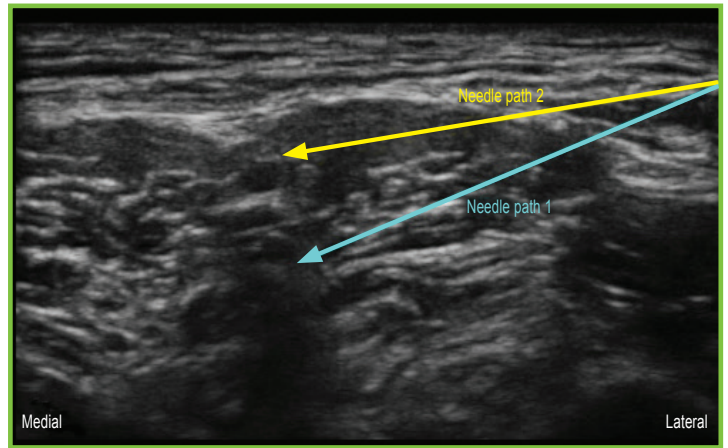


FIGURE. Interscalene brachial plexus nerve block ultrasound.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

Adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation.

Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia.

If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine.

EXPAREL is not recommended to be used in the following patient populations: patients <6 years old for infiltration, patients younger than 18 years old for interscalene brachial plexus nerve block, and/or pregnant patients.

Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease.

Warnings and Precautions Specific to EXPAREL

Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks **other than interscalene brachial plexus nerve block**, or intravascular or intra-articular use.

The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials.

Warnings and Precautions for Bupivacaine-Containing Products

Central Nervous System (CNS) Reactions: There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression.

Cardiovascular System Reactions: Toxic blood concentrations depress cardiac conductivity and excitability, which may lead to dysrhythmias, sometimes leading to death.

Allergic Reactions: Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients.

Chondrolysis: There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use.

Methemoglobinemia: Cases of methemoglobinemia have been reported with local anesthetic use.

Disclosure: Dr Hutchins is a paid consultant for Pacira BioSciences, Inc.

Full Prescribing Information is available at www.EXPAREL.com.