

Administration Case Report With EXPAREL

EXPAREL[®]
(bupivacaine liposome injectable suspension)

OPIOID FREE

This case report represents the individual experience of Dr Jeffrey C. Gadsden and is intended to demonstrate his methodology for using EXPAREL in a fascia iliaca field block.

Pacira Pharmaceuticals, 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 indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks.

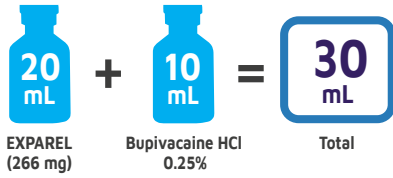
CASE INFORMATION

Physician Name	Jeffrey C. Gadsden, MD
Affiliation	Duke University Medical Center Associate Professor of Anesthesiology Chief, Division of Orthopedic, Plastic, and Regional Anesthesiology
Field Block Performed	Fascia iliaca field block
Inpatient or Outpatient Procedure	Inpatient in the Emergency Department (ED)

PATIENT CHARACTERISTICS

Gender	Female
Age	76 years
Patient History and Characteristics	<p>Patient has hypertension, type 2 diabetes mellitus, osteoarthritis, and is obese. She experienced a TIA in the remote past.</p> <p>Patient lives in a skilled nursing facility and ambulates with a walker. She was getting up to use the bathroom and tripped on the carpet, fracturing the left femoral neck.</p> <p>No loss of consciousness on arrival in the ED.</p> <p>In the ED, bloodwork was done, including CBC; an EKG was performed; and the anesthesia block team was called. As part of the hip fracture protocol, the anesthesiologist did a fascia iliaca block. The patient was then transferred to the preoperative holding area for planned surgery.</p>

PROCEDURAL DETAILS

Preoperative Analgesics Used	PO acetaminophen 925 mg PO pregabalin 75 mg
Field Block Performed	Suprainguinal fascia iliaca field block with 20 mL (266 mg) of EXPAREL admixed with 10 mL of 0.25% bupivacaine HCl
Dose of EXPAREL and Total Volume Used	 <p>20 mL EXPAREL (266 mg) + 10 mL Bupivacaine HCl 0.25% = 30 mL Total</p>

CBC, complete blood count; ED, emergency department; EKG, electrocardiogram; PO, by mouth; TIA, transient ischemic attack.

The recommended dose of EXPAREL 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.

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 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 physiochemical 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 the accompanying full Prescribing Information before using EXPAREL for complete Dosage and Administration information.

DR GADSDEN'S INFILTRATION TECHNIQUE

Dr Gadsden performed a fascia iliaca plane block using ultrasound guidance to ensure accuracy of infiltration underneath the fascia iliaca.

With the patient in the supine position, a linear high-frequency ultrasound transducer was placed over the inguinal region in the transverse orientation. After identification of the femoral artery and nerve, the transducer was translated laterally until the sartorius muscle was observed overlying the iliacus muscle. At this point, the transducer was rotated 90 degrees and moved cephalad past the inguinal ligament until the iliacus muscle was seen diving into the pelvis.

After sterile preparation of the skin, a 21-gauge, 10-cm block needle was inserted in-plane from the caudal aspect of the transducer and advanced under the fascia iliaca. A test injection with 3 mL of saline confirmed correct placement by the elevation of the fascia iliaca from the iliacus muscle.

After negative aspiration, an admixture of 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) (266 mg) and 10 mL of 0.25% bupivacaine HCl (25 mg) was administered slowly with periodic aspiration, maintaining the needle position throughout.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

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

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 population: patients <18 years old 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 Gadsden is a paid consultant for Pacira Pharmaceuticals, Inc.

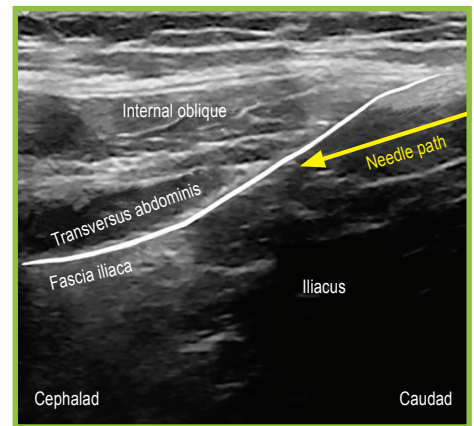


FIGURE. Fascia iliaca field block ultrasound.