Administration Case Report With EXPAREL

EXPAREL® (bupivacaine liposome injectable suspension)
OPIOID FREE

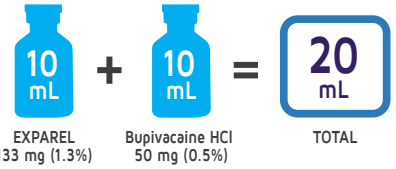
This case report represents the individual experience of Dr Maggie Holtz and is intended to demonstrate her methodology for using EXPAREL in a right total shoulder replacement procedure.

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	Maggie Holtz, MD
Affiliation	Chief of Regional & Orthopedic Anesthesia Georgia Anesthesiologists, P.C. WellStar Kennestone Regional Medical Center Marietta, GA
Surgical Case Performed	Right total shoulder replacement
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS	
Gender	Female
Age	87 years
Patient History and Characteristics	The patient presented with constant right shoulder pain that worsened with movement and had failed conservative therapy. Patient has a history of hypertension, hyperlipidemia, paroxysmal atrial fibrillation (currently in sinus rhythm), valvular heart disease (mild to moderate aortic insufficiency), and glaucoma.

PROCEDURAL DETAILS	
Preoperative Analgesics Used	IV acetaminophen 1000 mg PO gabapentin 300 mg PO celecoxib 400 mg
Nerve Block Performed	Interscalene brachial plexus nerve block with 10 mL (133 mg) of EXPAREL admixed with 10 mL of 0.5% bupivacaine HCl
Dose of EXPAREL and Total Volume Used	

IV, intravenous; PO, by mouth.

The recommended dose of EXPAREL for interscalene brachial plexus nerve block is based on one study of patients undergoing either total shoulder arthroplasty or rotator cuff repair. The maximum dose of EXPAREL for interscalene brachial plexus nerve block should not exceed 133 mg.

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 neurologic 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 for complete Dosage and Administration information before using EXPAREL.

DR HOLTZ'S INTERSCALENE BRACHIAL PLEXUS NERVE BLOCK TECHNIQUE

Step #1:

To identify the brachial plexus, the patient was placed in a semi-Fowler's position with a shoulder roll between the scapulae to facilitate exposure. Skin was prepped, and a linear high-frequency probe was placed on the patient's neck superior to the clavicle. The image was then traced cephalad until the brachial plexus was identified between the anterior and middle scalene muscles.

Step #2:

Under direct ultrasound visualization using an in-plane technique, Dr Holtz inserted a 20-gauge, 4-in echogenic needle from the lateral aspect of the transducer, through the middle scalene muscle, and advanced until the tip was just lateral to the brachial plexus between the C5 and C6 roots. After negative aspiration, Dr Holtz injected saline to confirm the desired placement of the needle tip. She then slowly administered an admixture of 10 mL of EXPAREL® (bupivacaine liposome injectable suspension) (133 mg) and 10 mL of 0.5% bupivacaine HCl (50 mg), with aspiration every 5 mL.

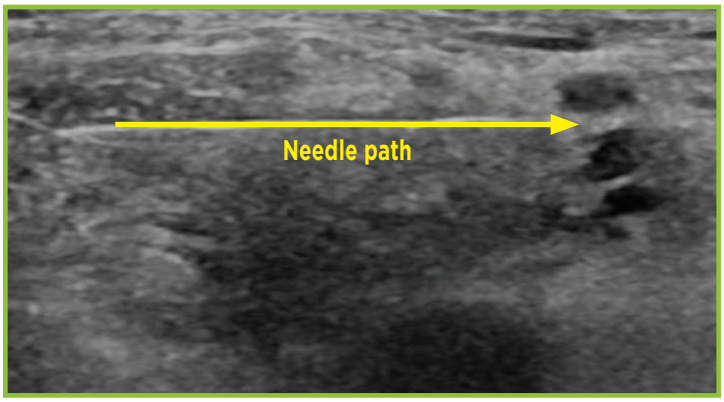


FIGURE. Interscalene brachial plexus nerve block ultrasound.

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 Holtz is a paid consultant for Pacira Pharmaceuticals, Inc.

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