NON-OPIOID
EXPAREL®
(bupivacaine liposome injectable suspension)

Administration Case Report: Lumbar Fusion With TLIP Block

This case report represents the individual experience of orthopedic spine surgeon Dr Alok Sharan, and is intended to demonstrate the methodology for using EXPAREL in patients undergoing a minimally invasive transforaminal lumbar interbody fusion (TLIF) with a thoracolumbar interfascial plane (TLIP) block.

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.

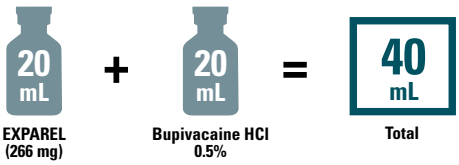
CASE INFORMATION

Physician Name	Alok Sharan, MD, MHCDS
Affiliation	Orthopedic Spine Surgeon, Director, Spine and Orthopedics NJ Spine and Wellness, Old Bridge, NJ
Surgical Case Performed	Minimally invasive TLIF with TLIP block
Inpatient or Outpatient Procedure	Outpatient

PATIENT CHARACTERISTICS

Gender	Male
Age	39 years
Patient History and Characteristics	Patient previously underwent microdiscectomy for a herniated disk. He presented with a reherniated disk 1 year later. Based on the patient's labor-intensive occupation, he elected to have a lumbar fusion

PROCEDURAL DETAILS

Incision Size	4-cm bilateral Wiltse incision
Dose of EXPAREL and Total Volume Used	
Intraoperative Anesthesia	Spinal anesthesia; 10 to 15 mg isobaric bupivacaine HCl 0.5%/fentanyl 25 µg

MULTIMODAL ANALGESIA AND ENHANCED RECOVERY AFTER SURGERY PROTOCOL

Preoperative Medications Used	PO oxycodone 10 mg
Intraoperative Medications Used	TLIP ultrasound-guided injection at L4 with 20 mL EXPAREL and 20 mL bupivacaine HCl 0.5%
Postoperative Medications Used	PO diazepam 2.5 mg q6h prn for the first 24 hours; PO oxycodone 5 mg or 10 mg/acetaminophen 325 mg q4h prn for moderate or severe breakthrough pain

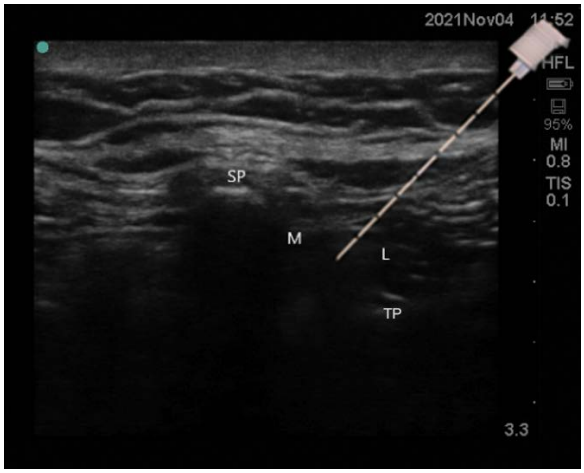
PO=by mouth; prn=as needed; q4h=every 4 hours; q6h=every 6 hours.

INFILTRATION NOTES

After induction of spinal anesthesia, Dr Sharan performed an ultrasound-guided bilateral TLIP injection at L4, with the patient in the prone position. Dr Sharan used a 40-mL total volume admixture of 20 mL of EXPAREL and 20 mL of bupivacaine HCl 0.5%, which was divided equally for bilateral injection.

Step #1:

Using a linear probe, Dr Sharan used a medial-to-lateral scanning technique to identify the L4 spinous process and transverse process (TP) in a transverse view on each side. The Multifidus muscle can be found directly lateral to the spinous process bilaterally and directly posterior to the lamina. The Longissimus muscle can be found lateral to the Multifidus muscle and posterior-lateral to the TP.



Step #2:

Using a lateral-to-medial needle approach, a 20-gauge, 4-inch echogenic needle was positioned within the fascial plane between the Multifidus (M) and Longissimus (L) muscles directly posterior to the ipsilateral TP. After negative aspiration, a test dose of 0.5 mL was injected to confirm the correct location. Then 15 mL of the EXPAREL admixture was injected at the interface between the Multifidus and Longissimus muscles, and 5 mL was infiltrated above the fascia. The same technique was used bilaterally.

Dr Sharan used a 4-inch echogenic needle advanced in plane to ensure adequate visualization on the ultrasound monitor and to provide sufficient needle depth to reach the interface between muscles.

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.

IMPORTANT SAFETY INFORMATION

Indication

EXPAREL® (bupivacaine liposome injectable suspension) is indicated for single-dose infiltration in patients aged 6 years and older to produce postsurgical local analgesia and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks.

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 Sharan is a paid consultant for Pacira BioSciences, Inc.

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