

Administration Case Report: Laminectomy and Fusion

This case report represents the individual experience of Dr Jeff Gadsden, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing laminectomy and fusion procedures.

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.

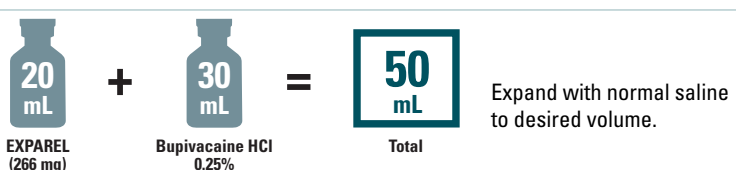
CASE INFORMATION

Physician Name	Jeff Gadsden, MD, FRCPC, FANZCA
Affiliation	Associate Professor of Anesthesiology, Duke University School of Medicine, Durham, NC
Surgical Case Performed	L3-L5 decompressive laminectomy and fusion
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	67 years
Patient History and Characteristics	Patient presented with failed conservative management of degenerative lumbar spinal stenosis at both L3-L4 and L4-L5 levels, with spondylolisthesis of L4-L5. Patient had been taking oxycodone 20 mg PO daily for the last 9 months. Past medical history included hypertension, obesity, and hypothyroidism

PROCEDURAL DETAILS

Incision Size	7-cm midline lumbar incision
Preoperative Analgesics Used	20 mL (266 mg) EXPAREL admixed with 30 mL of 0.25% bupivacaine HCl
Intraoperative Analgesics Used	IV ketamine 0.5 mg/kg bolus followed by 2 mcg/kg/min; IV dexamethasone 10 mg; IV fentanyl prn
Dose of EXPAREL and Total Volume Used	 <p>EXPAREL (266 mg) + Bupivacaine HCl (0.25%) = Total 50 mL</p> <p>Expand with normal saline to desired volume.</p>

IV=intravenous; PO=by mouth; prn=as needed.

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.

INFILTRATION NOTES

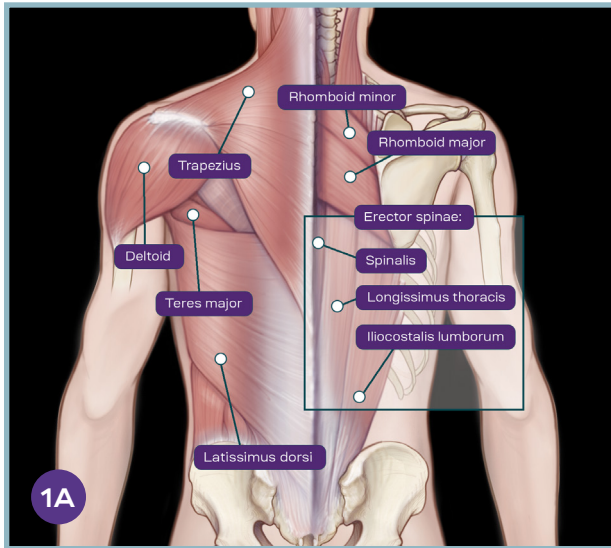


FIGURE 1A. Erector spinae muscle group

FIGURE 1B. Transducer and needle entry position for the ESP block at L4

- ESP blocks were performed in the preoperative block area. For this procedure, Dr Gadsden prepared 2 syringes of injectate, each containing 10 mL (133 mg) of EXPAREL[®] (bupivacaine liposome injectable suspension) and 15 mL (37.5 mg) 0.25% bupivacaine HCl
- The patient was positioned laterally with hips flexed, and midazolam 2 mg IV was administered for sedation
- A curvilinear ultrasound probe was placed in a parasagittal orientation and the transverse process of L4 identified underneath the erector spinae muscle group

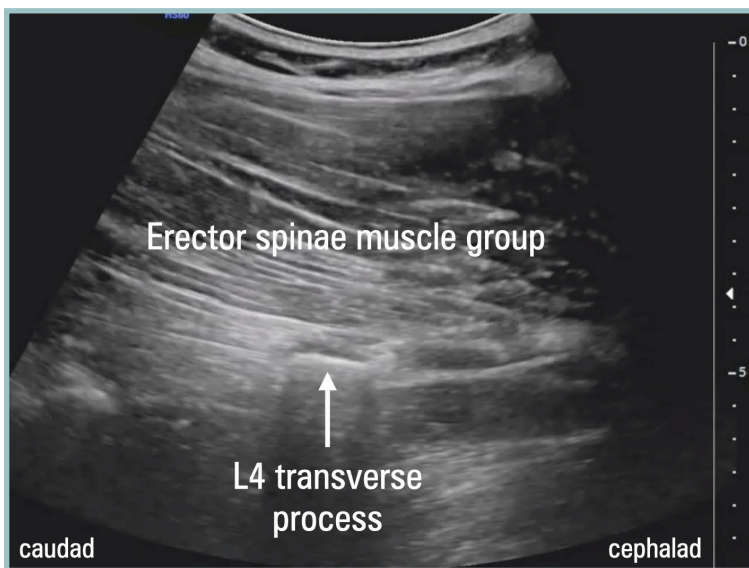


FIGURE 2. Sonoanatomy prior to needle insertion

- A 21-gauge, 100-mm needle was advanced from the cephalad aspect of the probe until contact was made with the transverse process

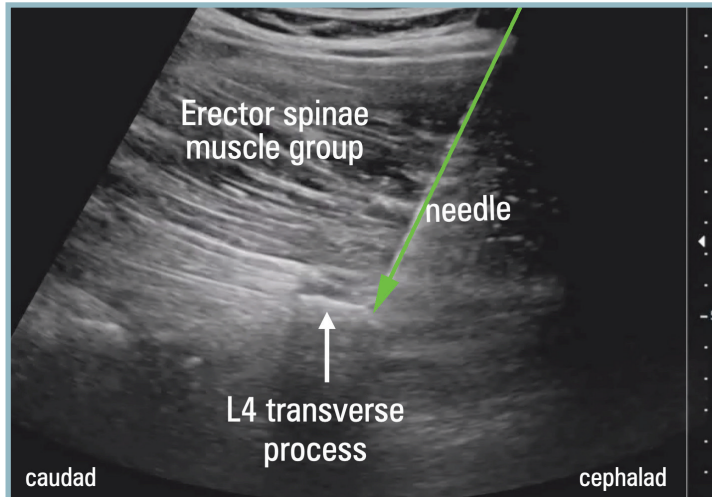


FIGURE 3. Needle contacting L4 transverse process

- Small boluses (1 mL) of saline were injected to confirm needle position underneath the deep fascia of the muscle, and the needle redirected to ensure the tip was not intramuscular. Once satisfied with needle position, 25 mL of the local anesthetic solution was slowly administered

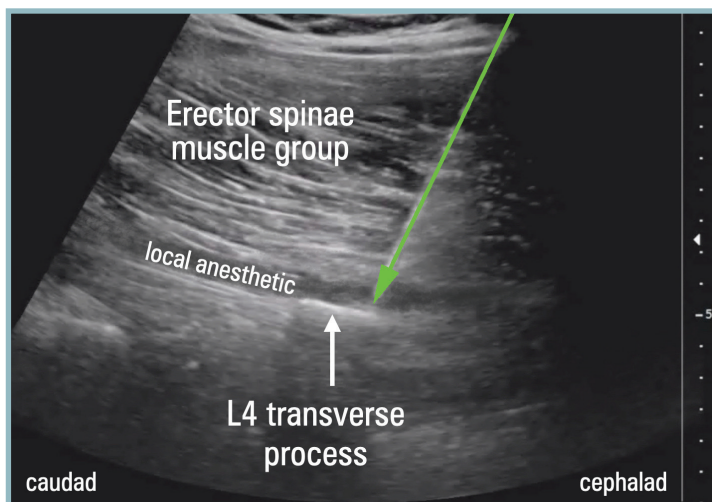


FIGURE 4. Pool of local anesthetic “lifting” the erector spinae muscle group off the transverse processes

- The correct injection plane was confirmed by observing cephalocaudal spread and a lifting of the muscle off the transverse process
- The block was then repeated on the contralateral side with 25 mL of the local anesthetic solution

TIPS

- The ESP block can be performed with the patient seated or in the lateral or prone position. Due to the nature of the surgical procedure and the potential disruption of fascial planes, ESP blocks for spine cases are best done preoperatively
- The ESP block should be performed at the midpoint of the expected surgical area (eg, for a L3-L5 laminectomy, depositing the local anesthetic at L4 provides coverage both cephalad and caudad. Dr Gadsden always consults with the surgeon ahead of time to confirm the surgical levels and approach
- Dr Gadsden always uses normal saline to hydrolocate the needle tip to ensure that the local anesthetic will be deposited deep into the erector spinae muscle group, not intramuscularly

IMPORTANT SAFETY INFORMATION

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 Gadsden is a paid consultant for Pacira BioSciences, Inc.

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