

Administration Case Report: Bilateral Inguinal Hernia Repair

This case report represents the individual experience of Dr Nihar V. Patel and is intended to demonstrate his methodology for using EXPAREL in a patient undergoing bilateral inguinal hernia repair for adolescent idiopathic non-incarcerated bilateral inguinal hernias.

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. When infiltrated in the fascial plane, it produces regional analgesia using regional techniques such as erector spinae plane (ESP) block, quadratus lumborum (QL) block, and transversus abdominis plane (TAP) block.

CASE INFORMATION

Physician Name	Nihar V. Patel, MD
Affiliation	Associate Professor of Anesthesiology Baylor College of Medicine/Texas Children's Hospital Houston, TX
Surgical Case Performed	Bilateral Inguinal Hernia Repair
Site of Care	Outpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	6 years
Weight	21.7 kg
Patient History and Characteristics	Otherwise healthy 6-year-old female with non-incarcerated bilateral inguinal hernias

PROCEDURAL DETAILS

Incision Size	2-cm incisions in the bilateral inguinal creases
Incision Type	Midline lateral
Preoperative Analgesics Used	None
Patient/Parent Education Regarding Pain Management	The intraoperative anesthesiologist explained to the family that a fascial plane block would be employed as a component of a comprehensive multimodal pain management plan.
Needle Size, Number of Syringes	2-inch 22-gauge echogenic needle from B. Braun used with 10 mL syringes (2) of local anesthetic injectate
Indicate Any Relevant Prep Instructions	After regional time out was conducted in the operating room prior to fascial plane blockade, the inguinal and infraumbilical abdominal wall were prepped with chlorhexidine solution.

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.

PROCEDURAL DETAILS

Admix or administer EXPAREL® (bupivacaine liposome injectable suspension) separately	EXPAREL admixed with 0.25% bupivacaine HCl*
Dosing and Administration	6.5 mL† of EXPAREL + 13.5 mL of 0.25% bupivacaine HCl = 20 mL of TOTAL injectate 10 mL of injectate used on each side block
Other Intraoperative Analgesics	IV dexmedetomidine 10 mcg IV morphine 2 mg IV ketorolac 10 mg

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.

IV=intravenous.

*Bupivacaine HCl is indicated for patients 12 years and older. The approach to using Bupivacaine HCl for this patient and procedure represents the individual clinical judgement of Dr Patel.

†EXPAREL is available in 10 mL and 20 mL vials.

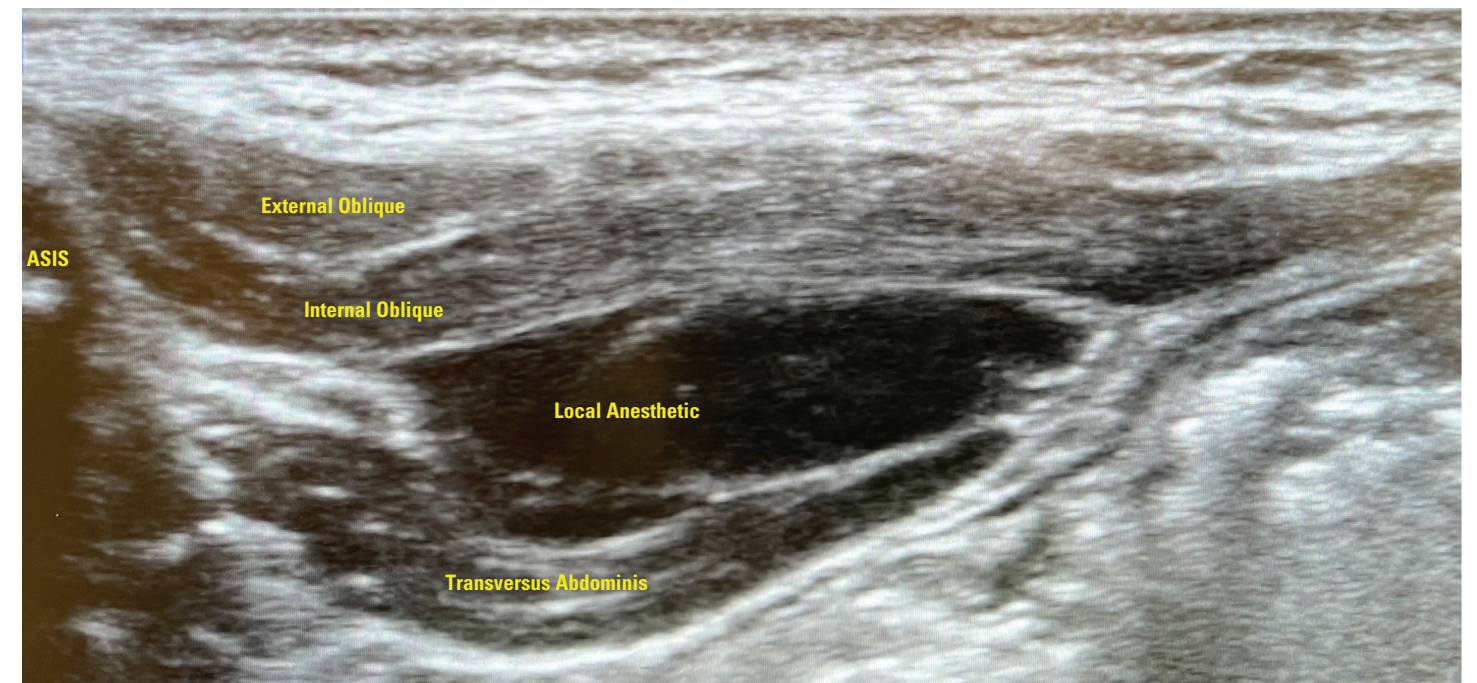
Please see Important Safety Information on page 6 and refer to accompanying full Prescribing Information, which is also available at www.EXPAREL.com.

INFILTRATION NOTES

For this procedure, a standard ilioinguinal/iliohypogastric fascial plane block was performed using ultrasound. An HFL50 15-6 MHz probe was placed in the inguinal region in an orientation from the umbilicus to the anterior superior iliac spine.



In the sonographic view below, the II/IH nerves were visualized in the fascial plane between the transversus abdominis muscle and the interior oblique muscle. A 2-inch 22-gauge echogenic B. Braun needle was used to deposit 10 mL of the local anesthetic admixture. The same injection was repeated on the contralateral side with another 10 mL of the local anesthetic admixture.



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Important Safety Information

EXPAREL® (bupivacaine liposome injectable suspension) 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 Nihar V. Patel is a paid consultant for Pacira BioSciences, Inc.

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