NON-OPIOID
EXPAREL®
(bupivacaine liposome injectable suspension)

Administration Case Report: Pediatric Tonsillectomy

This case report represents the individual experience of Dr Brent Feldt and is intended to demonstrate his methodology for using EXPAREL in patients undergoing a tonsillectomy.

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	Brent Feldt, MD
Affiliation	NorthBay Medical Center
Surgical Case Performed	Pediatric Tonsillectomy
Site of Care	Outpatient

PATIENT CHARACTERISTICS

Gender	Male
Age	8 years
Patient Weight	33 kg
Patient History and Characteristics	8-year-old male with history of snoring, witnessed breathing pauses during sleep, and excessive daytime fatigue.

PROCEDURAL DETAILS

Incision Size	Bilateral 2-cm oropharyngeal incision through the palatoglossus muscle and mucosa
Incision Type	Electrocautery
Preoperative Analgesics Used	Acetaminophen per rectum 480 mg (15 mg/kg)
Patient/Parent Education Regarding Pain Management	Discussed with the patient and parents that a local anesthetic will be injected after the tonsils are removed into the area where the tonsils were located. This medication is not intended to replace the weight-based oral pain medication that is prescribed following surgery, but can help provide extended pain relief.
Needle Size	Single 5-mL syringe with 25-g needle
Dosing and Administration	• 33 kg x 4 mg/kg = 132 mg • 132 mg ÷ 13.3 mg/mL = 9.9 mL of EXPAREL (Please refer to the Dosing and Administration Guide for calculations.)*  EXPAREL (133 mg)

*EXPAREL is available in 10-mL and 20-mL vials.

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.

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.

Please see Important Safety Information on page 4 and refer to accompanying full Prescribing Information, which is also available at www.EXPAREL.com.

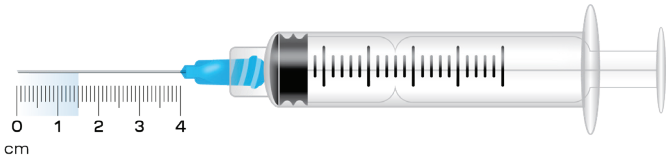
INFILTRATION NOTES

ASSESSED THE WEIGHT OF THE PATIENT, THE SURGICAL SITE, AND DEPTH OF TISSUE, THEN PREPARED INJECTION MATERIALS ACCORDINGLY

- For a 33-kg patient, the recommended dose (4 mg/kg) of EXPAREL® (bupivacaine liposome injectable suspension) is 132 mg, which is 9.9 mL of EXPAREL
- After tonsils were removed and homeostasis achieved, Dr Feldt assessed the surgical sites by palpating the tonsillar fossae to ensure no pulsations were palpable from the carotid artery or its branches
- EXPAREL was administered as follows*:
  - 2.5 mL administered into each mid-pole of the tonsillar fossae for a total of 5 mL to cover the tonsillar branch of the glossopharyngeal nerve
  - 2.4 mL in each of the superior poles of the tonsillar fossae close to the incision site (4.8 mL total) to provide coverage of the incision site(s)

Step 1:

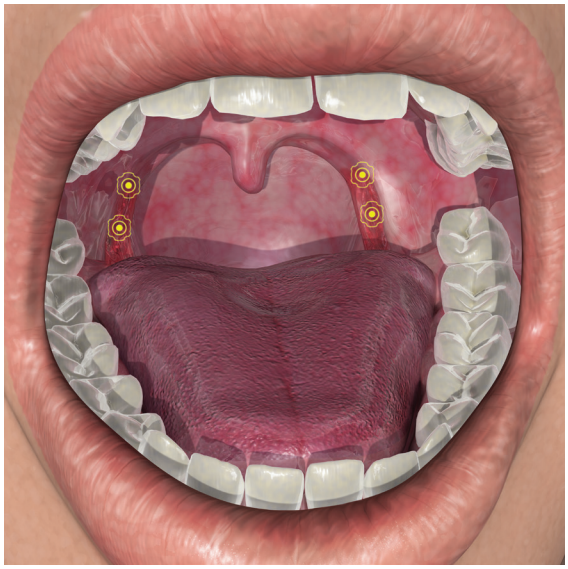
EXPAREL is placed into a 5-mL syringe with a 25-g needle. 25-g needle marked at 1.5 cm to demonstrate the depth of needle insertion into the pharyngeal muscle. (See image at right)



Contact your Pacira representative for dosing and administration guidance

Step 2:

Dr Feldt inserts the 25-g needle into the mid-pole of each tonsillar fossae and aspirates to ensure no intravascular injection; then he injects with 2.5 mL of EXPAREL into each tonsillar fossae. (See image at right)



Step 3:

Dr Feldt injects each bilateral incision site in the palatoglossus mucosa at the 1.5-cm needle depth with 2.4 mL of EXPAREL. (See image at right)

*Total 9.9 mL.

INFILTRATION NOTES (cont)

Step 4:

Any bleeding from the injection sites is controlled with electrocautery.

- Postsurgical pain control with weight-based oral ibuprofen and acetaminophen was an effective adjunct with EXPAREL® (bupivacaine liposome injectable suspension) injection following tonsillectomy
- Continuing the oral pain medication regimen and maintaining adequate hydration through 5 to 9 days following surgery helped patient maintain adequate oral intake
  - Adequate oral intake is an important aspect to maintain saliva lubrication, reduce infection, and despite significant odynophagia following the procedure, can help reduce pain during the time exudates are shed from the tonsillar fossae
- Follow-up in 4 to 6 weeks following surgery to determine improvement in sleep patterns

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 Feldt is a paid consultant for Pacira BioSciences, Inc.

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

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