

Administration Case Report: Total Ankle Arthroplasty

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

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 in adults via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and an adductor canal block.

CASE INFORMATION

Physician Name(s)	Jeff Gadsden, MD and James A. Nunley II, MD
Affiliation	Duke University Hospital, Durham, NC
Surgical Case Performed	Total ankle arthroplasty
Inpatient or Outpatient Procedure	Outpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	54 years
Patient History and Characteristics	This patient presented with longstanding pain and deformity in her ankle after a motor vehicle accident 20 years ago, and was scheduled for total ankle replacement surgery. Her medical history was otherwise unremarkable except for mild asthma. The anesthetic plan included a sciatic nerve block in the popliteal fossa and an adductor canal block, as well as intravenous sedation. For both nerve blocks, the plan was to use an admixture of EXPAREL and bupivacaine HCl.

PROCEDURAL DETAILS

Incision Type	Anterior approach between the tendons of the tibialis anterior and extensor hallucis longus
Preoperative Medications Used	<ul style="list-style-type: none">• Acetaminophen 975 mg PO• Midazolam 2 mg IV for procedural sedation• Fentanyl 50 mcg IV for procedural sedation/analgesia• EXPAREL 266 mg (20 mL) admixed with bupivacaine HCl 0.5% 100 mg (20 mL) for use as a sciatic nerve block in the popliteal fossa and an adductor canal block

IV=intravenous; PO=by mouth.

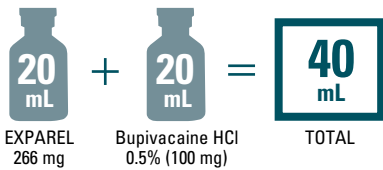
The recommended dose of EXPAREL for adults is based on the size of the surgical site, the volume required to cover the area, and individual patient factors that may impact the safety of an amide local anesthetic. The maximum dose of EXPAREL should not exceed 266 mg (20 mL). The recommended dose of EXPAREL for patients aged 6 to <17 years is 4 mg/kg, up to a maximum of 266 mg (20 mL). The recommended dose of EXPAREL in adults for interscalene brachial plexus nerve block and sciatic nerve block in the popliteal fossa is 133 mg (10 mL). The recommended dose of EXPAREL in adults for an adductor canal block is 133 mg (10 mL) admixed with 50 mg (10 mL) 0.5% bupivacaine HCl, for a total volume of 20 mL.

Please see Important Safety Information on the last page and full Prescribing Information at www.EXPARELpro.com.

PROCEDURAL DETAILS (CONT)

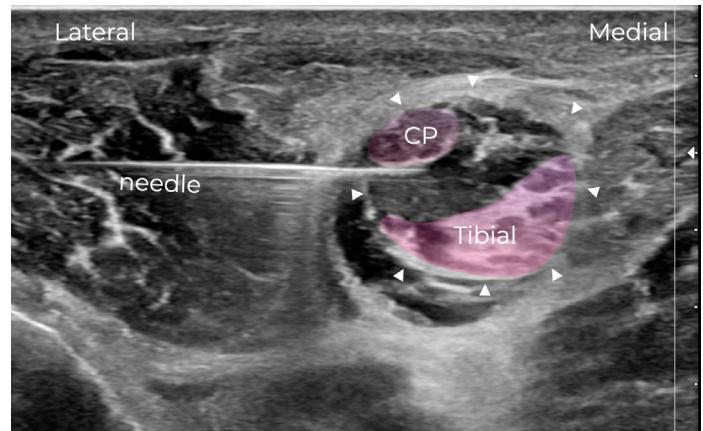
Intraoperative Medications Used	<ul style="list-style-type: none"> • Propofol 75-100 mcg/kg/min IV for sedation • Fentanyl 25 mcg IV prn for tourniquet discomfort
Postoperative Medications Used	<ul style="list-style-type: none"> • Acetaminophen 1000 mg PO QID • Oxycodone 5-10 mg PO q4-6h prn for breakthrough pain

EXPAREL ADMINISTRATION DETAILS

Dose of EXPAREL Used	266 mg (20 mL) used in 2 identical 20-mL syringes, each containing 133 mg (10 mL) and 10 mL 0.5% bupivacaine HCl (50 mg)
Did You Expand the Volume?	No
Did You Admix With Bupivacaine?	Yes, with 20 mL of 0.5% bupivacaine (100 mg)
Total Volume Used	 <p>EXPAREL 266 mg + Bupivacaine HCl 0.5% (100 mg) = TOTAL 40 mL</p>
Needle Used	100-mm 21-gauge block needle

STEP 1

With the patient in the lateral position and the operative side up, a linear ultrasound transducer was placed in a transverse orientation over popliteal fossa, aiming to image the popliteal artery, vein, and tibial nerve. The probe was then slid proximally until the common peroneal nerve was observed immediately lateral to the tibial nerve (ie, the bifurcation of the sciatic nerve). The goal is to perform the block at the location where the 2 nerves appear to be JUST separating but are both still within the connective tissue paraneural sheath.



STEP 2

A nerve stimulator was connected to a 21G 100-mm block needle and the current intensity set to 0.8-1.0 mA.

EXPAREL can be administered unexpanded (20 mL) or expanded to increase volume up to a total of 300 mL (maintain a minimum concentration of 0.89 mg/mL) 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 HCl, EXPAREL should not be admixed with other drugs prior to administration.

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ADMINISTRATION DETAILS (CONT)

STEP 3

After skin preparation and using sterile technique, the needle was advanced in-plane from the lateral aspect aiming to pierce the paraneural sheath between the 2 nerves. Care was taken not to contact either nerve directly. We then confirmed that an appropriate motor response (plantar flexion or dorsiflexion) was observed.



STEP 4

A test injection of 2 mL of saline confirmed that the needle tip was correctly placed within the sheath, and fluid was spreading immediately adjacent to one or both nerves. The local anesthetic mixture was then administered slowly and with intermittent aspiration, while maintaining the needle tip within the sheath. A total of 20 mL of the local anesthetic mixture was administered at this site. The needle was then withdrawn.

STEP 5

The patient was repositioned supine and the ultrasound transducer placed on the anteromedial thigh, aiming to visualize the femoral artery centered beneath the sartorius muscle. The saphenous nerve was visualized immediately lateral to the artery. After skin preparation and using sterile technique, the same block needle was advanced in-plane through the sartorius muscle, aiming for the saphenous nerve. A test injection of 2 mL of saline was used to confirm correct needle tip position, followed by administration of the remaining 20 mL of local anesthetic mixture.

ADDITIONAL NOTES

- Precision placement of the local anesthetic is critical to sciatic nerve block in the popliteal fossa success. We use small aliquots of saline to confirm that our needle tip is reliably within the paraneural sheath before commencing administration of the local anesthetic mixture. Extra-sheath administration of any local anesthetic will not be effective
- This block technique and local anesthetic mixture is sufficient to provide surgical anesthesia within 20 to 30 minutes. We always use propofol sedation for patient comfort and to prevent movement of the patient during the procedure
- We use a thigh tourniquet to provide hemostasis during total ankle arthroplasty.* During some longer procedures (>2-3 hr) it is common to encounter tourniquet pain and hypertension. This can be treated with small doses of IV fentanyl (eg, 25 mcg), IV ketamine (5-10 mg). Alternatively, a preoperative femoral artery block is commonly used in our institution to effectively anesthetize the afferent sympathetic fibers from the thigh, preventing tourniquet hypertension and sparing further opioid administration

*Wahal C et al. *Reg Anesth Pain Med.* 2021;46:228-232.

INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

EXPAREL[®] (bupivacaine liposome injectable suspension) is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older and regional analgesia in adults via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and an adductor canal block. 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 nerve block were nausea, pyrexia, headache, 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.

Do not admix lidocaine or other non-bupivacaine local anesthetics with EXPAREL. EXPAREL may be administered at least 20 minutes or more following local administration of 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 nerve blocks, 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, sciatic nerve block in the popliteal fossa, and adductor canal 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.

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

For more information, please visit www.EXPARELpro.com or call 1-855-793-9727.