

Administration Case Report: Cesarean Delivery

This case report represents the individual experience of Dr B. Wycke Baker, and is intended to demonstrate his methodology for using EXPAREL in a cesarean delivery.

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

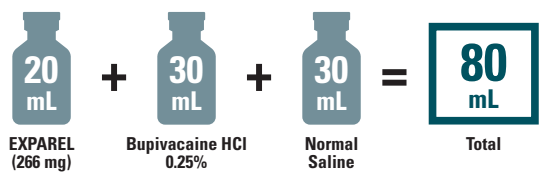
Physician Name	B. Wycke Baker, MD
Affiliation	Clinical Professor of Anesthesiology and Obstetrics/Gynecology Baylor College of Medicine, <i>voluntary faculty</i> Houston, TX
Surgical Case Performed	Cesarean delivery
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	38 years
Patient History and Characteristics	Patient had a range of comorbidities, including postsurgical nausea and vomiting, childhood asthma, and recent upper respiratory infection. G3P2, with 2 cesarean deliveries

PROCEDURAL DETAILS

Incision Size	12-cm Pfannenstiel
Preoperative Analgesics Used	Combined spinal/epidural anesthesia: hyperbaric bupivacaine 0.75% 13.5 mg + morphine 0.1 mg
Intraoperative Analgesics Used	80 mL of expanded EXPAREL
Postoperative Multimodal Medications Used	IV acetaminophen: 1 g IV first dose, then 1 g PO q6h*; IV ketorolac 30 mg q6h* (around the clock); PO ondansetron 4 mg q6h prn *Dose intervals were shingled so patient received alternating dose of IV acetaminophen or IV ketorolac q3h.

Dose of EXPAREL and Total Volume Used	 <p>20 mL EXPAREL (266 mg) + 30 mL Bupivacaine HCl 0.25% + 30 mL Normal Saline = 80 mL Total</p>
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IV=intravenous; PO=by mouth; prn=as needed; q3h=every 3 hours; q6h=every 6 hours.

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.

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

INFILTRATION NOTES

For this procedure, Dr Baker divided the injectate into four 20-mL syringes (20 mL per syringe). Using a 21-gauge, 110-mm Pajunk needle, he then performed an ultrasound-guided bilateral classic transversus abdominis plane (TAP) block. Starting at the right midaxillary line, the needle was advanced into the fascial plane through the external oblique and internal oblique muscles to the transversus abdominis muscle at the level of the T11 vertebra. After a negative aspiration, he infiltrated 40 mL into the TAP. Once completed, he repeated this on the left midaxillary line at the level of the T11 vertebra.

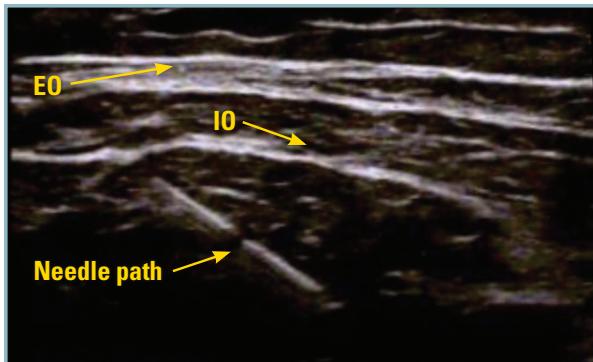


FIGURE 1. Needle placement

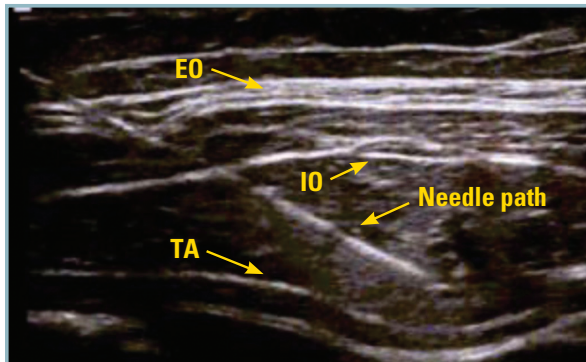


FIGURE 2. Infiltration



Be sure to aspirate prior to infiltration to avoid risk of intravascular injection.

EO=external oblique; IO=internal oblique; TA=transversus abdominis.

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 Baker is a paid consultant for Pacira BioSciences, Inc.

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