

Administration Case Report With EXPAREL

This case report represents the individual experience of Dr Andras Sandor and is intended to demonstrate his methodology for using EXPAREL in a specific soft tissue surgery.

Pacira Pharmaceuticals, 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 indicated for administration into the surgical site to produce postsurgical analgesia.

CASE INFORMATION

Physician Name	Andras Sandor, MD
Affiliation	Hallmark Health Lawrence Memorial Hospital, Medford, MA
Surgical Case Performed	Laparoscopic Sleeve Gastrectomy
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	42 years of age
Patient History and Characteristics	Morbid obesity with a BMI of 42, hypertension, obstructive sleep apnea

PROCEDURAL DETAILS

Incision Size	2-cm incision in right mid-abdomen (15-mm trocar); 1.2-cm incision 8 cm above the umbilicus in the midline (10-mm trocar for camera); 0.7-cm incisions in left upper quadrant (5-mm trocar), in the subxiphoid space (liver retractor) and in left lower quadrant (5-mm trocar)
Preoperative Analgesics Used	Acetaminophen 1000 mg IV at induction of analgesia
Intraoperative Analgesics Used	EXPAREL 266 mg (1 vial)
Was the Volume of EXPAREL Expanded? If So, to What Volume?	One 20 mL vial of EXPAREL expanded to 220 mL with preservative-free sterile normal saline

BMI, body mass index; IV, intravenous.

The recommended dose of EXPAREL 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.

EXPAREL can be administered undiluted (20 mL) or diluted 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 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 physiochemical 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 toxicity. Other than with bupivacaine, EXPAREL should not be admixed with other drugs prior to administration.

Please see Important Safety Information on reverse and refer to the accompanying full Prescribing Information before using EXPAREL for complete Dosage and Administration information.

INFILTRATION NOTES

ASSESSED SURGICAL SITES AND DEPTH OF TISSUES, THEN PREPARED INJECTION MATERIALS ACCORDINGLY

In this procedure, I determined I would need approximately 220 mL of EXPAREL solution, so I expanded 20 mL of EXPAREL with 200 mL of normal saline at the back table in a bowl. I then prepared two 20-mL syringes with 20-gauge 2-inch long needles attached. Using two 20-mL syringes allowed me to be more time efficient, because I could infiltrate with one syringe while simultaneously refilling the other.

PREEMPTIVELY INFILTRATED AREA AROUND EACH TROCAR SITE PRIOR TO INCISION AND TROCAR PLACEMENT (SEE FIGURE 1)

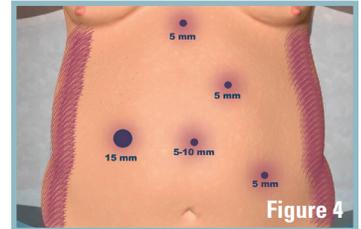
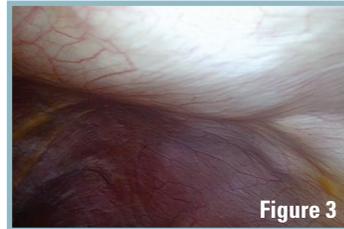
Prior to incision and trocar placement, I infiltrated the area around the intended trocar site in a 3-5 cm radius and into all layers of the abdominal wall (from the dermis to the preperitoneal space). I used approximately 10-15 mL of EXPAREL solution per trocar site.

PLACED THE 10-MM TROCAR IN THE EPIGASTRIC SPACE FOR THE VIDEO CAMERA, INSPECTED THE ABDOMINAL SPACE, AND PERFORMED BILATERAL INFILTRATION OF THE TRANSVERSUS ABDOMINIS PLANE (TAP) UNDER DIRECT LAPAROSCOPIC VISUALIZATION (SEE FIGURES 2 AND 3)

When infiltrating the TAP, I began in the mid-axillary line, starting underneath the rib-cage and extending to the iliac crest. I used a small volume of EXPAREL solution for each injection, and focused on directing the EXPAREL solution to create contiguous coverage between the rib cage and the iliac crest on both sides of the abdomen (see Figure 4).

I then used the remaining EXPAREL solution to broadly infiltrate the area around each trocar site in the same plane. I used approximately 10-15 mL of EXPAREL solution per trocar site.

I administered EXPAREL immediately prior to surgery to maximize its effect by the end of the operation, and supplemented with IV administration of a non-steroidal anti-inflammatory agent, such as ketorolac or acetaminophen, during surgery.



Important Safety Information:

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. EXPAREL has not been studied for use in patients younger than 18 years of age.

Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Formulations of bupivacaine other than EXPAREL should not be administered within 96 hours following administration of EXPAREL.

Monitoring of cardiovascular and neurological status as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products.

Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations.

In clinical trials, the most common adverse reactions (incidence $\geq 10\%$) following EXPAREL administration were nausea, constipation, and vomiting.

Disclosure: Dr Sandor is a paid consultant for Pacira Pharmaceuticals, Inc.