

Administration Case Report: Laparoscopic Sleeve Gastrectomy

This case report represents the individual experience of Dr Brian R. Binetti, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing laparoscopic sleeve gastrectomy.

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.

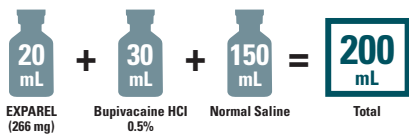
CASE INFORMATION

Physician Name	Brian R. Binetti, MD, FACS
Affiliation	Director of Metabolic and Bariatric Surgery, Health Quest Medical Practice, Northern Dutchess Hospital, Rhinebeck, NY
Surgical Case Performed	Laparoscopic sleeve gastrectomy
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	60 years
Patient History and Characteristics	Morbidly obese (BMI 46.9 kg/m ²) Comorbidities include hypertension and obstructive sleep apnea requiring CPAP
Pathology	Morbid obesity

PROCEDURAL DETAILS

Incision Size	5 total port sites: 4 × 5 mm, 1 × 12 mm
Preoperative Analgesics Used	IV acetaminophen 1000 mg IV ketorolac 15 mg
Intraoperative Analgesics Used	200 mL of expanded EXPAREL for TAP blocks (150 mL) and port site infiltrations (50 mL)
Dose of EXPAREL and Total Volume Used	 <p>20 mL EXPAREL (266 mg) + 30 mL Bupivacaine HCl 0.5% + 150 mL Normal Saline = 200 mL Total</p>

BMI=body mass index; CPAP=continuous positive airway pressure; IV=intravenous.

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.

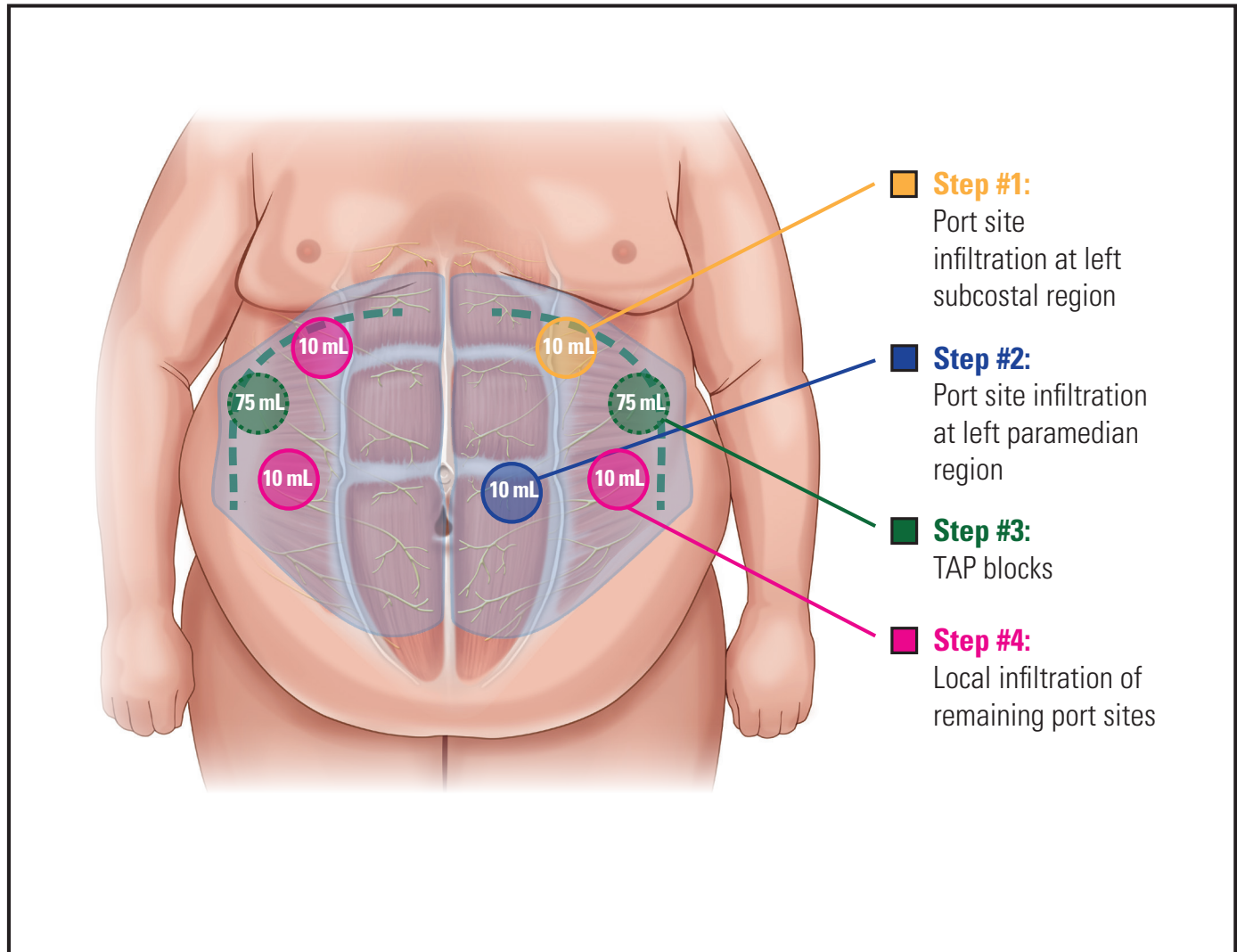
INFILTRATION NOTES

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

In this procedure, prior to the gastric bypass, Dr Binetti determined that a total volume of 200 mL would be needed for the TAP blocks (150 mL) and port site (50 mL) infiltrations. He expanded 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 150 mL of normal saline and then admixed 30 mL of 0.5% bupivacaine HCl. In larger patients, Dr Binetti ensures he has adequate volume by expanding with additional normal saline for a total volume of up to 300 mL. Dr Binetti added bupivacaine HCl to provide short-term local analgesia that overlapped with the long-term local analgesia provided by EXPAREL.

DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE GAUGES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLANNED WHICH AREAS TO INFILTRATE WITH EACH INJECTION

For this procedure, Dr Binetti identified and marked key landmarks (xiphoid process, subcostal margins, midaxillary line, iliac crests) to assist with the TAP blocks and port site placements. He then divided the injectate into syringes and, using 22-gauge spinal needles, infiltrated as follows:

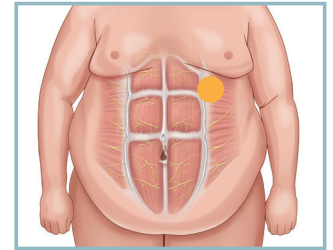


INFILTRATION NOTES (cont)

■ Step #1: Port Site Infiltration at Left Subcostal Region

Dr Binetti infiltrated 10 mL of expanded EXPAREL® (bupivacaine liposome injectable suspension) into the left subcostal region prior to making a 5-mm incision. A Veress needle was then inserted, and the abdominal cavity was inflated with carbon dioxide.

Once the pneumoperitoneum was created, a 5-mm port was inserted under direct visualization. A 5-mm scope was then inserted to ensure that the port site infiltrations, port site placements, and TAP blocks were performed under direct visualization.

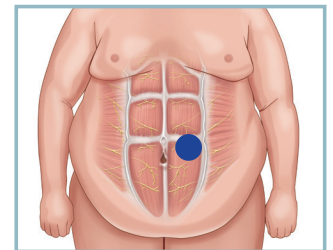


10 mL into 5-mm incision site

With each port site infiltration, inject the needle down to the preperitoneal space, then slowly withdraw to the dermis level. The goal is to create a column of EXPAREL injectate from the preperitoneal space up to the dermis for maximal analgesic coverage.

■ Step #2: Port Site Infiltration at Left Paramedian Region

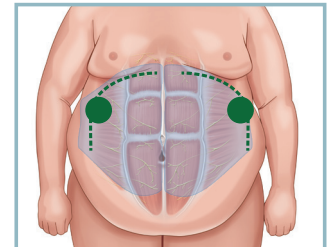
Dr Binetti infiltrated 10 mL of expanded EXPAREL into the left paramedian region prior to making a 12-mm incision. Following incision, a 12-mm port was inserted.



10 mL into 12-mm incision site

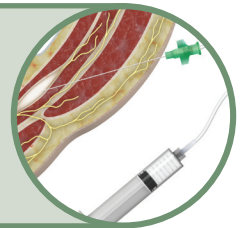
■ Step #3: TAP Blocks

Starting at the right TAP, Dr Binetti infiltrated 35 mL of expanded EXPAREL along the right subcostal margin and 40 mL of expanded EXPAREL along the right midaxillary line, ending at the right iliac crest, for a total of 75 mL. He injected 2 to 3 mL every 1 to 2 cm along the plane. He then repeated this technique when infiltrating into the left TAP for a total of 150 mL of expanded EXPAREL for the TAP blocks.



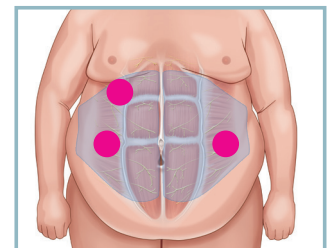
75 mL per TAP block (150 mL total)

Laparoscopic view of a smooth transversus abdominis muscle bulge indicates that the needle penetration is at the appropriate depth and the injectate is in the TAP. This should be done under direct visualization to ensure that the needle does not penetrate the peritoneum.



■ Step #4: Local Infiltration of Remaining Port Sites

Finally, Dr Binetti infiltrated 30 mL of expanded EXPAREL into the remaining port sites, using 10 mL at each of the three 5-mm port sites.

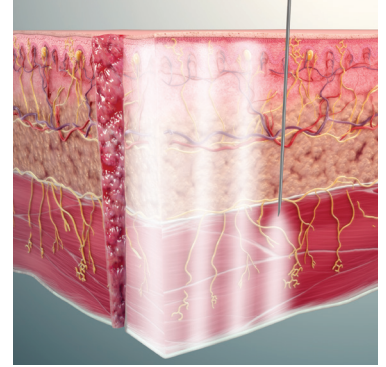


30 mL into remaining port sites

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

Dr Binetti infiltrated EXPAREL® (bupivacaine liposome injectable suspension) into each port site with a moving needle technique. The needle was injected down to the preperitoneal space and slowly withdrawn to the dermis level. With a moving needle technique, the injections were spread in a fan-like pattern as the needle was withdrawn to maximize the coverage area. The goal was to create a column of EXPAREL injectate from the preperitoneal space up to the dermis for maximal analgesic coverage.



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 Binetti is a paid consultant for Pacira BioSciences, Inc.

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