Lap band with hiatal hernia repair

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CASE PRESENTATION
A 46-year-old male with history of morbid obesity (144 kg, 6'1", BMI 41.8) was unresponsive to conservative therapy. Past medical history included morbid obesity, hypertension, obstructive sleep apnea, diabetes mellitus, gastro-esophageal reflux disease, low back pain and hiatal hernia. His social history included no tobacco use and occasional alcohol consumption.

RECOMMENDED PROCEDURE
Laparoscopic gastric band placement and hiatal hernia repair
• Via 4 small incisions (5mm-12mm), the stomach was mobilized. The hiatal hernia was repaired and gastric band was placed on proximal stomach. Sutures were used to tack stomach portions around band to help prevent slippage.
• Duration of procedure was 54 minutes.

PATIENT’S PERIOPERATIVE ANALGESIC PROTOCOL
† Patient took 3 doses of PO hydrocodone/acetaminophen elixir on POD 0
• Do not exceed the recommended maximum daily limits of acetaminophen by all routes

INDICATIONS AND USAGE
OFIRMEV® (acetaminophen) injection is indicated for the management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

IMPORTANT RISK INFORMATION
WARNING: RISK OF MEDICATION ERRORS AND HEPATOTOXICITY
Take care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death. In particular, be careful to ensure that:
• the dose in milligrams (mg) and milliliters (mL) is not confused;
• the dosing is based on weight for patients under 50 kg;
• infusion pumps are properly programmed; and
• the total daily dose of acetaminophen from all sources does not exceed maximum daily limits.

OFIRMEV contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product.

Please see additional Important Risk Information on reverse and in accompanying Full Prescribing Information.

* This case study is intended only to provide healthcare professionals with an example of the use of OFIRMEV (acetaminophen) injection in the treatment of one specific patient. The outcomes described may not be representative of, and may differ significantly from, outcomes that may be obtained in treating other patients. This case study is not intended to provide specific treatment advice, recommendations, or opinions, and should not replace a clinician’s judgment with respect to the treatment of any particular patient.
**Pain Assessment**

- PACU: 4/10 on arrival
- PACU: 2/10 prior to discharge home

*Based on a 10-point visual analog scale (VAS).

**Patient Ambulation/Discharge**

- Patient ambulated 100 yards on PostOp Day 0
  - Early ambulation is encouraged from the moment the patient wakes up as it helps decrease the pain from CO₂ in the abdomen and further helps prevent the likelihood of DVTs.
  - The patient was discharged from the PACU for barium swallow 34 minutes after arrival. The patient needs to ambulate adequately to and from radiology.
  - The patient was discharged home 73 minutes after arrival in PACU.
  - During a follow-up visit two weeks after surgery, the patient stated he had excellent pain control with a rating of 2/10 VAS score with pain mainly at the port site.

**Important Risk Information**

**Contraindications**

- Acetaminophen is contraindicated in patients with:
  - known hypersensitivity to acetaminophen or to any of the excipients in the intravenous (IV) formulation.
  - severe hepatic impairment or severe active liver disease.

**Warnings and Precautions**

- Administration of acetaminophen in doses higher than recommended may result in hepatic injury, including the risk of liver failure and death. Do not exceed the maximum recommended daily dose of acetaminophen. The maximum recommended daily dose of acetaminophen includes all routes of acetaminophen administration and all acetaminophen-containing products administered, including combination products. Dosing errors could result in accidental overdose and death.
  - Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia (e.g., due to dehydration or blood loss), or severe renal impairment (creatinine clearance ≤ 30 mL/min).
  - Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Hypersensitivity and anaphylaxis associated with the use of acetaminophen have been reported. Clinical signs included swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, and pruritus. The antipyretic effects of OFIRMEV may mask fever.
  - **Serious adverse reactions** may include hepatic injury, serious skin reactions, hypersensitivity, and anaphylaxis. **Common adverse reactions** in adults include nausea, vomiting, headache, and insomnia. **Common adverse reactions** in pediatric patients include nausea, vomiting, constipation, pruritus, agitation, and atelectasis.

**Use in Specific Populations**

- Pregnancy: Pregnancy Category C. OFIRMEV should be given to a pregnant woman only if clearly needed.
- Breast Feeding: While studies with OFIRMEV have not been conducted, acetaminophen is secreted in human milk in small quantities after oral administration.
- Pediatrics: The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients < 2 years of age.

Please see additional Important Risk Information, including boxed warning, on reverse side and in accompanying Full Prescribing Information.
5 WARNINGS AND PRECAUTIONS

3.2 Serious Skin Reactions

5.3 Risk of Medication Errors

7.2 Anticoagulants

6.4 Hypersensitivity

5.2 Hepatic Injury

8.2 Patients with Hepatic Impairment

5.1 Acute Liver Failure

4. CONTRAINDICATIONS

2.1 General Dosing Information

5.4 Use in Specific Populations

4.1 Hypersensitivity, including anaphylaxis

2.2 Recommended Doses: Adults and Adolescents

2.3 Recommended Dose: Children

5.1 Acute Liver Failure

3.3 Risk of Medication Errors

2.2 Recommended Dosing: Adults and Adolescents

5.1 Hepatic Injury

2.1 General Dosing Information

5.1 Acute Liver Failure

3.3 Risk of Medication Errors

2.2 Recommended Dosing: Adults and Adolescents

5.1 Acute Liver Failure

2.1 General Dosing Information

5.1 Acute Liver Failure

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2.1 General Dosing Information
There are no adequate and well-controlled studies with percentage of abnormal sperm, and reduced birth weights in mating pair occurred during lactation and post-weaning at all and 1.7 times the MHDD, respectively, based on a body 0.25, 0.5, or 1.0% acetaminophen via the diet (357, 715, or the MHDD, based on a body surface area comparison. external, visceral, or skeletal malformations. When pregnant and rudimentary rib changes). Offspring had no evidence of up to 0.85 times the maximum human daily dose (MHDD = increase its hepatotoxic potential. The clinical consequences CYP2E1 may alter the metabolism of acetaminophen and associated with hepatic damage in 90% of patients; potentially fatal hepatic necrosis is the most serious adverse effects on small-vessel hemostasis. Clinical studies of both the rat model (3.6-times the MHDD, based on a body surface area comparison), suggesting a threshold effect. No overall differences in safety or effectiveness were seen in children age 2 years and older. The pharmacokinetics of OFIRMEV have been studied in both healthy subjects and patients with hemophilia showed no significant changes in bleeding time after repeated dosing of acetaminophen may be warranted. Acetaminophen is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used only with caution in patients with chronic active liver disease (see Warnings and Precautions (7.1) and of the analgesic and antipyretic properties of acetaminophen is not established but is thought to be in neonates up to 28 days, with a minimum dosing interval of 6 hours, will produce a pharmacokinetic exposure Parameters of OFIRMEV (AUC, C max, terminal half-life (T ½), systemic clearance (CL), and volume of distribution (Vss) are provided in Table 4. Pharcokinetic study of OFIRMEV showed that the maximum concentration (C max) occurs at the end of the 15-minute acetaminophen oral dose administration of OFIRMEV. Compared to the same dose of oral acetaminophen, the C max, following a single 650 mg dose of OFIRMEV was 4.38 mg/mL, and 2.74 mg/mL at 4 hours post ingestion. After ingestion. Early signs of potential hepatotoxicity include nausea, vomiting, anorexia, delirium, and general malaise. Clinical evidence of liver toxicity may not be apparent until 48 to 72 hours following ingestion. OFIRMEV overdose is suspected, obtain a serum acetaminophen as soon as possible, but no sooner than 4 hours after ingestion (oral). Activated charcoal is not recommended initially, and repeated studies usually start at 42 hours after ingestion. Administer the antidote if acetaminophen (NAC) as early as possible to treatment of acute ingestion, the acetaminophen level can be plotted against time since oral ingestion. Use in children >12 years of age, the liver is the major site of biotransformation of acetaminophen (10 mg/mL) in cartons of 24 vials. USP Controlled Room Temperature®. Acetaminophen metabolites are mainly excreted in the urine. The mean temperature over time is shown in Figure 1.

Acetaminophen was not mutagenic in the bacterial reverse mutation assay (Salmonella). In contrast, acetaminophen tested positive in the in vitro mouse lymphoma assay and the in vitro chromosomal aberration assay using human lymphocytes. In clinical Pharmacology (12.1). A reduced total daily dose of acetaminophen may be warranted. 8.5 Geriatric Use While studies with OFIRMEV have not been conducted in neonates, there is evidence that small-vessel hemostasis may be impaired in adult patients treated with OFIRMEV, which may result in an increased risk of major and minor bleeding, including hip or knee replacement. OFIRMEV was statistically superior to placebo for reduction in pain intensity over 24 hours. There was an attendant decrease in opioid consumption, the clinical benefit of which was not demonstrated. Pain Study 2 evaluated the analgesic efficacy of repeated doses of OFIRMEV 1000 mg every 6 hours or 650 mg every 4 hours for 24 hours plus placebo in the treatment of 244 patients with moderate to severe postoperative pain after abdominal laparoscopic surgery. Patients receiving OFIRMEV experienced a statistically significant greater pain reduction in pain intensity over 24 hours compared to placebo. 14.2 Adult Fever The efficacy of OFIRMEV 1000 mg in the treatment of adult fever was evaluated in randomized, double-blind, placebo-controlled clinical trials. The study was a 6-hour, single-dose, endoscopy-induced fever study in healthy adult males. A statistically significant antipyretic effect of 1000 mg OFIRMEV was demonstrated in through comparison to placebo.