Rotator cuff repair surgery

David S. Brown, PA-C, Tri-State Orthopedics and Sports Medicine, Pittsburgh, PA

CASE PRESENTATION
A 49-year-old, 104 kg, right-hand dominant male presented with an acute right rotator cuff tear. His past medical history includes hypertension and GERD. Social history includes occasional alcohol use; patient stated no tobacco or illicit drug use. Patient X-ray revealed Type II acromion; otherwise negative. MRI showed acute tears of supraspinatus and infraspinatus tendons with approximately 1 cm of retraction.

DIAGNOSIS AND RECOMMENDED PROCEDURE
• Right shoulder arthroscopic subacromial decompression and rotator cuff repair
• Anesthesia
  − Single shot interscalene nerve block
  − Received midazolam, fentanyl and propofol for sedation and anesthesia
  − Multimodal postoperative pain management

PATIENT’S PERIOPERATIVE ANALGESIC PROTOCOL

<table>
<thead>
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<tbody>
<tr>
<td>Interscalene nerve block: ropivicaine 0.5%</td>
<td>40 mL</td>
<td></td>
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<tr>
<td>IV midazolam</td>
<td>2 mg</td>
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<tr>
<td>IV fentanyl</td>
<td>50 μg</td>
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<td></td>
</tr>
<tr>
<td>IV propofol</td>
<td>100 mg</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>OFIRMEV® (acetaminophen) injection</td>
<td>1 g</td>
<td>1 g</td>
<td>(4h after IntraOp dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PO oxycodone</td>
<td>5 mg</td>
<td>5 mg</td>
<td>5 mg</td>
<td>5 mg</td>
<td>5 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 tabs q4h)</td>
<td></td>
<td>(1 tab q6h)</td>
<td>(1 tab q6-8h)</td>
<td>(1 tab BID)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PO acetaminophen (extended release)</td>
<td>650 mg</td>
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</table>

• Do not exceed the recommended maximum total daily dose of acetaminophen by all routes. The maximum total daily dose of OFIRMEV for adults ≥ 50kg is 4000 mg.

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.
# PostOp Outcomes

<table>
<thead>
<tr>
<th>PAIN ASSESSMENT*</th>
<th>OPIOID CONSUMPTION</th>
<th>PATIENT SATISFACTION</th>
</tr>
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</table>
| • Patient stated he had no pain PostOp at rest but did have pain in the first 2 PostOp days during sleep hours and for the first 4 days of physical therapy.  
  – PACU discharge score: 0/10  
  – PostOp Day 1-2: 6-7/10  
  – PostOp Day 3-4: 5-6/10  
  – PostOp Day 5-6: 4-5/10  
  – PostOp Day 7-8: 2-3/10 | • PO oxycodone  
  – PostOp Day 1-2: 10 mg q4h  
  – PostOp Day 3: 5 mg q6h  
  – PostOp Day 4: 5 mg q6-8h  
  – PostOp Day 5-6: 5 mg BID | • “Good” rating for pain control on a 4-point categorical scale |

*Based on an 11-point numeric rating scale (NRS).

## PATIENT DISCHARGE

- Discharge  
  – Discharged same day as surgery (normal institution protocol for rotator cuff surgery)  
  – At the time of discharge patient did not require pain medication
- Physical Therapy  
  – Started physical therapy on PostOp Day 2 and reported maximum pain at 7/10 while in therapy requiring opioid use.
- Follow-up on PostOp Day 13  
  – Pain score of 1-2/10 while in physical therapy  
  – Not using medicine for pain

## 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 \( \leq 30 \text{ mL/min} \)).
- 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.
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.

OFIRMEV (acetaminophen) injection is indicated for the treatment of acute pain or fever. No dose adjustment is recommended for patients weighing 50 kg or less.

DOSAGE AND ADMINISTRATION

2.2 Recommended Dosage: Children

Children 2 to 12 years of age: 10 to 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours, with a maximum single dose of 4000 mg per day (up to 3750 mg).

The following additional treatment-emergent adverse reactions were reported by pediatric subjects treated with OFIRMEV (see Table 3). The most common adverse events (incidence ≥ 5%) in pediatric patients treated with OFIRMEV were:

Bacterial and fungal sepsis, nasopharyngitis, headache, and urticaria.

Table 1. Dosing for Adults and Adolescents

<table>
<thead>
<tr>
<th>Age group</th>
<th>Dose given</th>
<th>Dose given as a single dose (mg)</th>
<th>Maximum single dose (mg)</th>
<th>Maximum total daily dose (mg)</th>
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<tr>
<td>Adults</td>
<td>1000</td>
<td>1000</td>
<td>4000</td>
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</tr>
<tr>
<td>Adolescents</td>
<td>15 mg/kg</td>
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Precautions

Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active liver disease (including chronic liver disease), pregnancy, cardiopulmonary disease, decompensated cirrhosis, hepatocellular carcinoma, and hepatorenal syndrome (hyponatremia, e.g., due to dehydration or blood loss), or severe renal impairment (creatinine clearance ≤ 30 mL/min) (see Tables 3 and 4).

Table 2. Dosing for Children

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Gastrointestinal disorders

138 (54) 119 (31) 62 (23)

Vomiting

30 (10) 14 (5) 6 (2)

Diarrhea

47 (16) 30 (10) 8 (3)

Table 3. Treatment Emergent in 2% of OFIRMEV-treated Patients

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Reproductive, therapeutic and medicinal disorders: pulmonary edema, hypoxia, pleural effusion, shunt, wheezing
Skin and subcutaneous tissue disorders: petechial eruption, ecchymosis
Vascular disorders: hypertension, hypotension

7 DRUG INTERACTIONS

7.1 Effects of other Substances on Acetaminophen

Reducing the dose of acetaminophen by 33% in infants 1 month to < 2 years of age, greater (based on a body surface area comparison) result in decreased testicular weights, reduced spermatogenesis, and greater (based on a body surface area comparison) result in reduced fertility, and reduced implantation sites in females in decreased testicular weights, reduced spermatogenesis, and greater (based on a body surface area comparison) result in reduced fertility, and reduced implantation sites in females.

12.1 Mechanism of Action

Acetaminophen has been shown to have analgesic and antipyretic effects in animal and human studies. Single doses of OFIRMEV up to 3000 mg and repeated doses of 1000 mg every 6 hours for 48 hours have not been shown to cause a significant effect on platelet aggregation. In general, the risk of any immediate or delayed effects on small-vessel hemostasis. Clinical studies of both healthy subjects and patients with hemophilia showed no significant changes in bleeding time after receiving multiple doses of OFIRMEV.

Distribution

The pharmacokinetics of OFIRMEV have been studied in patients and healthy subjects from premature neonates up to adults 60 years old. The pharmacokinetic profile of OFIRMEV is similar to that observed in children age 2 years and older. The pharmacokinetic exposure of OFIRMEV observed in children and adolescents is similar to adults, but the pharmacokinetic exposure of OFIRMEV observed in children and adolescents is similar to adults, but the pharmacokinetic exposure of OFIRMEV observed in children and adolescents is similar to adults, but the pharmacokinetic exposure of OFIRMEV observed in children and adolescents is similar to adults.

The pharmacokinetic exposure of OFIRMEV is not significantly affected by renal or hepatic impairment or severe active liver disease and should not be used in patients with hepatic insufficiency. In patients with mild, moderate, or severe hepatic insufficiency, acetaminophen has been shown to have analgesic and antipyretic properties of acetaminophen is not established but is thought to primarily involve central actions.

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