

Special REPORT

Over-the-Counter Analgesics for The Management of Acute Pain: *Clinical Experience in the Era of the Opioid Crisis*

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This supplement was funded by Johnson & Johnson Consumer Inc. McMahon Publishing developed the content with input and editorial review by Johnson & Johnson Consumer Inc.

Key Highlights

- Recognition of the underlying causes of opioid abuse has resulted in the reevaluation of opioid-sparing pain management practices in the United States, and has given rise to multimodal regimens using 2 or more pharmacologic and nonpharmacologic options as a standard approach for optimal pain control.
- Over-the-counter (OTC) analgesics can play an important role in multimodal pain management strategies. A review of currently available clinical efficacy and safety data is provided regarding the appropriate use of OTC analgesics, both on their own and within multimodal regimens.
- Case studies are presented demonstrating use of OTC analgesics by health care professionals in various real-world clinical scenarios.

Providing effective pain management can be complicated: Patient characteristics¹; the type, cause, and duration of the pain²; access to appropriate medications and therapies³; and discrepancies in pain assessment and reporting⁴ can affect outcomes. Untreated and/or ineffectively treated acute or postoperative pain can have long-term consequences for patients, including delayed healing, reduced quality of life, enhanced central nervous system sensitization leading to chronic pain conditions, and increased economic burden (ie, longer hospital stays).^{5,6} Financially, in the United States, indirect costs associated with untreated pain, such as

functional disability and lost productivity, among others, can reach \$335 billion annually.⁷

Effective pain management with analgesics and non-pharmacologic therapies can become difficult to achieve when patients in pain have limited access to appropriate care or are limited by government or private insurance carriers to certain medications or reduced dosages.^{8,9} Among health care professionals, lack of education on various pain states and management options, as well as a reluctance in prescribing opioids,¹⁰ also may lead to increased incidence of untreated pain. If opioids are prescribed, patients may be uninformed about the risk for

adverse events (AEs) or dependence, and expectations regarding the results of treatment.^{11,12} Lastly, pain assessment tools used in everyday practice do not always reflect the patient's quality of life or include a functional outcomes component.¹³ Because pain is subjective for both the patient and health care professional,⁴ measures of pain can be diminished by individual perceptions and varying pain thresholds, potentially further reducing the adequacy of treatment in appropriately controlling pain.¹⁴

Thus, a need exists for effective pain treatment options that can be adapted depending on the pain type or patient characteristics, which may reduce the reliance on any single agent, including opioids, and are available and accessible to patients. This special report reviews the evolving field of pain management and its adoption of multimodal pain management regimens including recommendations for use of OTC medications, such as acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), to address the complexities of treatment.

Shift to Multimodal Pain Management

Opioids are a mainstay of treatment in acute¹⁵ and post-surgical pain¹⁶ despite the incidence of opioid-related adverse events (ORAEs), such as sedation, ileus, and respiratory depression.¹⁷ During the past 5 years, widespread use of opioids has been subject to scrutiny due to the incidence of diversion, misuse, and addiction.^{18,19} In the United States, 335,000 overdose deaths due to prescription and illicit opioids were reported between 2001 and 2016.¹⁹

Although use of opioids continues to be a major component of appropriate pain management plans for specific patients,^{15,16} the ramifications of the opioid crisis have prompted health care professionals and institutions to evaluate and adopt integrative therapies, including opioid-sparing multimodal pain management regimens. As defined, multimodal regimens use multiple analgesics and/or techniques with differing mechanisms of action to create greater potential additive or synergistic effects for improved pain relief than single-agent regimens.²⁰ Nonopioid pharmacologic options can include acetaminophen, NSAIDs—such as ibuprofen, naproxen, ketorolac, and diclofenac—corticosteroids, lidocaine, menthol, camphor,

gabapentin, and pregabalin, among others, supplied in both oral and topical formulations.²⁰⁻²² Nonpharmacologic options may include neurostimulation, behavioral techniques, physical therapy, exercise, acupuncture, diet modification, sleep hygiene, and others (Table 1).²⁰⁻²³

Guidelines for Pain Management

In their joint clinical practice guideline for the management of postoperative pain, the American Pain Society (APS), the American Society of Regional Anesthesia and Pain Medicine (ASRA), and the American Society of Anesthesiologists (ASA) recommend a multimodal pharmacologic and nonpharmacologic approach, and outline how optimal management starts in the perioperative period where a care plan is tailored to the individual patient and/or procedure based on patient assessment.²⁰ The Enhanced Recovery After Surgery (ERAS) Society has developed multimodal approach protocols to reduce patient stress and ensure homeostasis following surgery; for example, their guidelines for perioperative care in elective rectal/pelvic surgery include postoperative use of nonopioids.²⁴

In response to the opioid epidemic, the CDC issued updated guidelines in March 2016 for chronic noncancer pain, indicating that opioids should not be first-line or routine treatment options.²⁵ According to these guidelines, health care professionals should discuss goals of treatment and establish follow-up plans and tapering protocols when prescribing medication. If needed, the smallest quantity of opioids required should be prescribed, and opioids should be initiated at the lowest effective dosage for the shortest amount of time. Patients should be monitored closely for misuse.²⁵ Subsequently in 2018, the Department of Health and Human Services, Department of Defense, and Department of Veterans Affairs; other governmental agencies; and academia as well as patient advocates and experts in pain conditions—working as the Pain Management Best Practices Inter-Agency Task Force²⁶—posted draft recommendations online that recognize that opioid use disorder is a failure of pain management, and address gaps or inconsistencies of existing clinical practices for managing both acute and chronic pain.²⁷ The recommendations include the need for increased physician training in pain management, patient education, adoption of a multidisciplinary approach, and nonmedicinal complementary therapies, increased access to care, and research.²⁷

Multimodal Versus Single-Agent Regimens

Although studies comparing specific multimodal and single-agent regimens are limited, available data show increased pain relief and a reduced AE profile—compared with opioids alone—when multimodal treatment is used for peri- and postoperative, acute, and chronic pain.²⁸⁻³¹

A recent, large-scale (N=1,318,165), population-based study of multimodal analgesia used following total hip and total knee arthroplasties found that patients receiving multimodal therapy had lower amounts of opioids prescribed perioperatively, reduced hospital length of stay, and lower costs of hospitalization than those receiving only opioids.²⁸ Studies in acute pain have shown positive improvements in pain scores and ratings of patient satisfaction in the hours after surgery or intervention following trauma using an opioid-sparing, multimodal approach that included prescription and OTC analgesics.^{29,31}

Chronic pain data have shown similar utility of multimodal treatment.³⁰ In 406 patients experiencing painful diabetic

Table 1. Nonopioid Pharmacologic and Nonpharmacologic Treatment Options in Multimodal Pain Management

Pharmacologic	Nonpharmacologic
Acetaminophen	Acupuncture
Aspirin	Behavioral techniques
Camphor ^a	Chiropractic
Clonidine	Diet modification
Corticosteroids ^a	Exercise
Gabapentin	Massage
Lidocaine ^a	Neurostimulation
Menthol ^a	Physical therapy
NSAIDs (ibuprofen, naproxen, diclofenac ^a)	Sleep hygiene
Pregabalin	

^a Available in topical formulation.

NSAIDs, nonsteroidal anti-inflammatory drugs

Based on references 20-23.

neuropathy for at least 3 months, the coadministration of gabapentin and prolonged-release oxycodone versus gabapentin alone showed a statistically significant reduction in pain scores (mean pain score reduction, 33%).³² Patient ratings of medication efficacy were higher for those taking the multimodal regimen of an opioid and nonopioid versus those receiving a single medication for pain.³²

Overall, the optimal drug and/or nonpharmacologic therapy combination for each patient and pain type is unknown.²⁸ As multimodal regimens use various drug classes and several options within class, health care professionals should have an understanding of the efficacy data, administration, and safety of each potential medication to ensure adequate pain relief is provided with reduced AEs.

OTC Analgesics: Efficacy and Safety Profile Reviews

Significant clinical literature examining the efficacy and safety of acetaminophen and NSAIDs in the treatment of mild to moderate pain relief is available. The clinical studies highlighted below are not an exhaustive review, and health care professionals should consider that the use of OTC products may depend on the type of pain, individual patient characteristics, and the relevant product indications.

Acetaminophen

Acetaminophen is a centrally acting analgesic and antipyretic agent, the exact mechanism of action of which is unknown. There is evidence that acetaminophen exerts its effect by inhibiting the formation and release of prostaglandins, which elevates the pain threshold and has antipyretic effects.³³ Acetaminophen is an effective and generally affordable OTC medication that is safe when used as directed.^{34,35} Acetaminophen is indicated for temporary relief of minor aches due to the common cold, arthritis, headache, backache, toothache,

premenstrual and menstrual cramps, and muscular aches as well as temporary fever reduction.³⁶

As shown in Table 2, the recommended OTC dose of acetaminophen for adults is 650 mg every 4 to 6 hours or 1,000 mg every 6 hours (maximum daily dose = 3,250 or 3,000 mg, respectively). For the extended-release formulation, the dose is 1,300 mg every 8 hours (maximum daily dose = 3,900 mg).³⁷⁻⁴² If pain or fever persists at the total labeled daily dose, health care professionals may exercise their discretion and recommend up to 4,000 mg per day.³⁷

Efficacy

Acetaminophen 1,000 mg was found to be superior to acetaminophen 650 mg in the treatment of postoperative pain after dental surgery,³⁴ with dental pain being a longtime standard model for the effectiveness of analgesia.⁴³ In patients treated in the emergency department for acute pain from soft tissue injuries, acetaminophen was comparable to ibuprofen, diclofenac, and indomethacin in immediate pain relief.⁴⁴ In one study, acetaminophen also was shown to be comparable to ibuprofen for pain relief and improvement in physical function and range of motion in osteoarthritis (OA) of the knee.⁴⁵

In a study of 61 patients with limb fractures, those using patient-controlled analgesia (PCA; morphine) were randomly assigned to receive either acetaminophen 1,000 mg or placebo every 4 hours, with their pain level assessed every 72 hours.³¹ Results found that patients receiving acetaminophen had a lower pain score on day 1 than the placebo group (2.1 vs 3.3 for placebo, on an 11-point scale; $P=0.03$). Decreased PCA use also was found among acetaminophen patients, compared with placebo (35.8 vs 45.5 hours; $P=0.03$).³¹

Safety Profile

Although acetaminophen has been shown to be associated with severe liver damage or renal impairment in doses

Table 2. Over-the-Counter Analgesic Dosage Chart^a

Analgesic	Amount Per Pill	Dose and Frequency	Daily Dosage Limit ^b	Daily Limit (No. of pills in 24 h)
Acetaminophen (extended release)	650 mg	2 pills every 8 h	3,900 mg ^c	No more than 6
Acetaminophen (extra strength)	500 mg	2 pills every 6 h	3,000 mg ^c	No more than 6
Acetaminophen (regular strength)	325 mg	2 pills every 4-6 h	3,250 mg ^c	No more than 10
Aspirin (extra strength)	500 mg	1 or 2 pills every 4-6 h	4,000 mg	No more than 8
Aspirin (regular strength)	325 mg	1 or 2 pills every 4 h, or 3 pills every 6 h	4,000 mg	No more than 12
Ibuprofen	200 mg	1 pill every 4-6 h ^d	1,200 mg ^e	No more than 6
Naproxen sodium	220 mg	1 pill every 8-12 h ^f	660 mg ^e	No more than 3 (No more than 2 pills in any 8- to 12-h period)

^a For adults and children 12 years of age and older.

^b Do not exceed the dose on the label directions.

^c Professional discretionary dosing. If pain or fever persists at the total labeled daily dose, health care professionals may exercise their discretion and recommend up to 4,000 mg/day.

^d While symptoms last (if pain or fever does not respond to 1 pill, 2 pills may be used).

^e Unless directed by a doctor.

^f While symptoms last (for the first dose, you may take 2 pills within the first hour).

Based on references 37-42.

exceeding the maximum daily dose of 4,000 mg in 24 hours,³³ it has a favorable safety profile,^{34,35} particularly in patients with preexisting gastrointestinal (GI) or renal conditions exacerbated by NSAIDs.^{5,20}

NSAIDs

Nonselective NSAIDs exert their nociceptive effects via inhibition of the cyclooxygenase-2 (COX-2) enzyme and a decrease in prostaglandin synthesis.^{16,17} COX-2 inhibition decreases central and peripheral pain sensitization, attenuates the inflammatory response, and improves pain control.⁴⁶ Early, perioperative administration of NSAIDs also has been shown to have opioid-sparing effects after major surgery.⁴⁷

OTC NSAIDs are indicated for mild to moderate aches and pains due to headache, backache, toothache, muscular and menstrual pains, minor pain of arthritis, and the common cold as well as the temporary reduction of fever.⁴¹ Different NSAID formulations have unique dosage strengths and instructions. OTC ibuprofen is available in a 200-mg dose to be taken every 4 to 6 hours with a daily maximum of 1,200 mg,⁴¹ whereas the recommended naproxen dosing is 220 mg every 8 to 12 hours, not to exceed 660 mg daily (see Table 2).^{41,42} NSAID prescription dosages typically range much higher than OTC formulations; for example, oral and IV ibuprofen doses range from 400 to 800 mg every 4 to 6 hours depending on pain severity, up to 3,200 mg daily.^{48,49} The increased drug amount should prompt health care professionals to monitor patients taking prescription doses more closely for NSAID-related AEs.

Efficacy

In a meta-analysis comparing pain relief outcomes between placebo, aspirin, and various NSAIDs, including ibuprofen and diclofenac, among women with primary dysmenorrhea pain, results found that several NSAIDs provided superior pain relief over aspirin and all were superior to placebo.⁵⁰ When reviewing patients' need for rescue analgesia, the study also found that patients receiving various types of NSAIDs required less additional rescue medication compared with placebo and aspirin. Naproxen and ibuprofen, among others, also scored significantly higher improvements in pain scores compared with placebo.⁵⁰ In acute pain, data from third molar extraction studies showed that several OTC products were highly efficacious, particularly the NSAIDs ibuprofen, naproxen, and diclofenac.⁵¹

A placebo-controlled study assessed the effectiveness of ibuprofen 1,200 mg, acetaminophen 1,950 mg, and naproxen sodium 750 mg in reducing the severity of orthodontic (after separator placement) pain (n=24).⁵² Patients who received ibuprofen reported significantly less pain than those who received placebo at 2 and 6 hours after separator placement.⁵²

Safety Profile

In patients with preexisting coagulation problems, a health care professional's guidance should be sought before using NSAIDs, as these drugs are associated with an increased risk for bleeding, including GI bleeding. Other conditions in which NSAIDs should be used with caution are GI ulceration, renal dysfunction, cardiac conditions, and liver disease.²⁰ Selective COX-2 inhibitors, such as prescription celecoxib, have been shown to be gentler on the stomach than nonselective NSAIDs.^{20,22}

Acetaminophen and NSAID Society Recommendations

Many organizations have published clinical practice guidelines to help guide health care professionals in their treatment of patients with pain. For example, guidelines published by several professional organizations have listed acetaminophen and topical NSAIDs as the initial pharmacologic treatment for the symptoms of mild to moderate joint pain of OA. The American College of Rheumatology Guidelines for the Medical Management of Osteoarthritis, which were updated in 2012, conditionally recommend OTC acetaminophen for the initial management of knee and hip OA at up to 4,000 mg per day at the discretion of the health care professional.⁵³ For individuals not achieving a satisfactory clinical response to acetaminophen 4,000 mg per day, NSAIDs, tramadol, or intra-articular corticosteroid injections are recommended for those aged older than 75 years, those with contraindications to these agents, or those with various complications including history of symptomatic GI ulcer, concomitant daily low-dose aspirin, and underlying kidney disease.⁵³

Guidelines published by the European League Against Rheumatism (EULAR) recommend acetaminophen as the oral analgesic to try first for knee and hip OA; if successful, EULAR recommends using acetaminophen as the preferred long-term oral analgesic because of its safety and efficacy profiles.^{54,55} Topical NSAIDs also have been recommended by EULAR for pain control in specific joints.⁵⁴

The United Kingdom's National Institute for Health and Clinical Excellence 2014 clinical guideline recommends that health care professionals should consider offering acetaminophen for pain relief in addition to core treatments; regular dosing may be required.⁵⁶ Acetaminophen and/or topical NSAIDs should be considered ahead of oral NSAIDs, COX-2 inhibitors, or opioids.⁵⁶

Guidelines published by the American College of Physicians and the APS identify acetaminophen and NSAIDs as a reasonable first-line analgesic choice for low back pain.⁵⁷ The American College of Occupational and Environmental Medicine identifies acetaminophen as a first-line option to use in patients with contraindications for NSAIDs, with low back disorders, chronic low back pain, postoperative low back pain, and radicular pain.⁵⁸

Additionally, multiple NSAIDs have been shown to provide positive efficacy for migraine treatments (ie, reducing migraine attack frequency, number of migraine-days, attack severity), thus leading to the American Academy of Neurology and the American Headache Society to recommend their use be considered for patients experiencing migraines.⁵⁹

Acetaminophen and NSAIDs Within Multimodal Regimens

Adequate pain control is an important concern to patients and health care professionals, in addition to achieving functional outcomes, particularly in acute and postoperative settings where insufficient pain management may complicate recovery and delay discharge.⁶⁰ As referred to above, health care professionals have OTC pain relief options, such as acetaminophen and NSAIDs, that are indicated for minor aches and pain to consider as part of a multimodal regimen. Although combination therapy including acetaminophen or NSAIDs with opioids has produced differing results depending on the study,

most data indicate a benefit to the use of nonopioid agents as part of pain treatment.

Curatolo and Svetcic reviewed 55 studies related to the treatment of acute postoperative pain and showed that the combination of acetaminophen and NSAIDs was superior to either drug alone. Also, combining NSAIDs with morphine provided clinically beneficial outcomes.⁶¹ In a recent article published by *JAMA*, Chang et al found no statistically significant or clinically important differences in pain reduction using either an acetaminophen-ibuprofen combination or an opioid-acetaminophen combination for acute pain after admission to the emergency department.¹⁵ In addition, the authors noted that no recent postoperative or dental pain study has found a benefit to the use of combination acetaminophen and codeine 30 or 60 mg over a combination of acetaminophen (in doses ranging from 325-1,000 mg) and ibuprofen 400 mg (non-OTC) in these settings.¹⁵

Other studies have found that when taken with morphine, both acetaminophen and NSAIDs were shown to decrease opioid requirements, and NSAIDs were shown to improve clinically meaningful outcomes as measured by a reduction in pain intensity on the visual analog scale.⁶² A meta-analysis review of 52 randomized, placebo-controlled clinical trials in acute postoperative pain showed that when combining NSAIDs with opioids, the addition of NSAIDs significantly decreased pain intensity. Morphine consumption also was shown to be reduced when NSAIDs or acetaminophen were given in conjunction with the opioid.⁶² NSAIDs significantly decreased the incidence of postoperative nausea, vomiting, and sedation, but increased the risk for surgical bleeding.⁶² Additionally, combination therapy with acetaminophen and NSAIDs has been associated with a higher risk for blood loss in patients with OA and knee pain than those receiving monotherapy. This result increased when combination therapy was taken for 13 weeks.⁶³

The effectiveness of nonopioids for perioperative pain has led to their wide-scale adoption in ERAS protocols; acetaminophen, celecoxib, and gabapentin have been shown to be the most commonly used nonopioid medications in ERAS multimodal pain management regimens.⁶⁴

Educating Patients and Managing Expectations On the Use of OTC Analgesics

When prescribing OTC analgesics, health care professionals should consider a comprehensive patient history, including comorbidities, concurrent and past medications, and prescriptive and herbal supplements. For example, conditions including stomach ulcers; hypertension, heart attack, or stroke; and liver disease can put patients at increased risk for AEs from NSAIDs.⁶⁵ In this respect, pain management can be challenging in elderly patients who may have multiple comorbidities, such as cardiovascular diseases, or musculoskeletal, renal, or cognitive impairments.³

Patients must be aware of other concomitant medications, such as aspirin and other NSAIDs, warfarin, steroids, or hypertension and asthma medications. For example, acetaminophen might be present in common OTC cough and cold products, sleep aids, or allergy or antipyretic medications (Table 3).⁶⁶ Cardiovascular risk may warrant the use of acetaminophen instead of NSAIDs.²⁰ There also is an increased risk for bleeding if NSAIDs are taken with blood-thinning (anticoagulant)

drugs, steroids, other NSAIDs, or if patients consume 3 or more alcoholic drinks per day.⁶⁷ Acetaminophen product labeling instructs patients to ask a doctor or pharmacist before use if taking the blood-thinning drug warfarin. In addition, serious liver damage may occur if more than 4,000 mg of acetaminophen is taken in 24 hours; if acetaminophen is taken with other products containing acetaminophen; or if 3 or more alcoholic drinks are consumed every day while taking acetaminophen.³⁶

As every patient will have an individual perception of pain,¹⁶ physicians and other health care professionals must reset patient expectations regarding pain after surgery, levels of pain that are acceptable for adequate function, and pain that does not require pharmacologic treatment. Health care professionals must address any patient perception that OTC analgesics are not effective in reducing mild to moderate pain and should communicate the benefits of OTC analgesics, such as lack of a risk for addiction, effectiveness for pain reduction, and reduced risk for AEs and drug-drug interactions, depending on the administered dose.⁴⁴ Such discussion can be the first step in developing a written multimodal pain management plan with patients.

Online resources including Get Relief Responsibly (GetReliefResponsibly.com and GetReliefResponsiblyProfessional.com) can be helpful for patients and health care professionals to obtain information about OTC analgesics. The website outlines doses of acetaminophen, aspirin, and

Table 3. Patient-Directed Education on Acetaminophen Dosing, Safety, and Efficacy

Patients may accidentally exceed the recommended dose by taking more than 1 acetaminophen-containing product at a time, not realizing the products contain the same ingredient.

Some patients exceed safe doses by not reading the dosing directions.

Taking more acetaminophen than directed (more than 4,000 mg in 24 h) may lead to liver damage.

Check the active ingredients in all medicines patients take. Acetaminophen is in more than 500 OTC and prescription medicines.

Take only 1 medicine that contains acetaminophen at a time.

Be especially cautious during cold and flu season, because cold/flu products and sleep aids often contain acetaminophen.

If patients are not sure which pain reliever to choose or how to use it, they should consult with you or another health care professional first.

When taken as directed, acetaminophen can provide safe, effective pain relief.

Choosing an OTC pain reliever carefully—and using it as directed—is important to patients' health.

OTC, over-the-counter

Based on reference 66.

NSAIDs for children and adults with respective indications and undesirable effects. If OTC medications are prescribed in dosages or regimens beyond what is indicated on the label, it is important that patients only take these amounts under care from a health care professional. For pain control outside this scope, they should always read and follow the US Drug Facts label. Fact sheets, tables, graphics, and a multimodal pain management planner to facilitate practical application can be shared to help patients best understand the appropriate use of OTC analgesics.⁶⁸

Conclusion

Pain affects a significant proportion of the population,²³ and there is an increasing need to manage it effectively. A culture

shift in pain management has been set and reinforced by updated CDC recommendations,²⁵ which will continue to evolve in 2019 and beyond with publication of the Pain Management Inter-Agency Task Force guidelines.²⁷ Governmental agencies, professional organizations, and insurers have made efforts nationally to modify prescription practices and ensure the delivery of safe analgesia.²⁷ Professional societies have recommended the use of multimodal pain management strategies that include OTC medications, such as acetaminophen and NSAIDs, in various clinical settings. Guidelines promote methods that decrease the reliance on opioids, and stress patient education and engagement in the treatment plan.²⁰ As these guidelines evolve, so too should health care professional messages and patient education.

Utilization of Acetaminophen in Postoperative Pain Management

Srinivas Nalamachu, MD

Every year in the United States, millions of patients undergo surgical procedures in both outpatient and inpatient settings. Postoperative pain can last a few days to a few weeks, depending on the procedure. The severity of pain can vary from mild to moderate or severe based on the extent of tissue trauma sustained by the patient during the procedure.¹⁶

Management of postoperative pain is critical for a number of reasons, including the following:

1. early mobility and ambulation;
2. early discharge from the hospital;
3. ability to tolerate physical rehabilitation;
4. return to work and improvement of function; and
5. prevention of the development of chronic pain.

Our surgical colleagues primarily manage postoperative pain unless the pain lasts beyond its usual course, at which point, patients may be referred to pain clinics for further evaluation and management. Traditionally, the use of short-acting opioids has been the primary mode of pain control in postoperative pain management.¹⁶ However, evidence shows that short-acting opioids used for an extended period of time could lead to addiction and abuse, and surveys have shown that the majority

of recreational users report obtaining their opioids from friends or family who originally received the prescription from their health care provider.⁶⁹ Although we have a moral and ethical obligation to manage postoperative pain appropriately, we must consider risk management as part of the prescribing of opioids as well as management of potential ORAEs.

In our clinical practice, we try to minimize the frequency and duration of opioid use by incorporating other nonopioid agents early in the process. This can help minimize the risk for opioid-induced ileus and the ability to operate a motor vehicle without worrying about drowsiness or confusion.

NSAID use for the management of postoperative pain is always a challenge because of concerns for bleeding and drug–drug interactions with anticoagulants.⁶⁷ Because of the various risks associated with opioids and NSAIDs,^{5,17,20} acetaminophen is a proven option for postoperative pain management in combination with opioids for moderate to severe pain or as monotherapy for mild to moderate pain. Because acetaminophen is an OTC analgesic, it is convenient for patients since they can acquire it without a prescription; it can spare them a follow-up visit to the clinic for a new prescription; and they can self-titrate based on their pain experience with the guidance of their provider.

Efficacy, Safety, and Patient Education of OTC Analgesics

Susan Pendergrass, MSN, MEd, FNP-BC

How to provide adequate pain management continues to be challenging for some health care professionals. Multimodal, opioid-sparing options continue to evolve for acute, chronic, persistent, and mixed pain states. OTC analgesics, such as acetaminophen and NSAIDs, play an important role in managing pain, but consumer and/or patient education remains important to help ensure the efficacy and safe use of these products.

Development and recognition of updated guidelines by organizations such as the APS, ASA, ASRA, and CDC support multimodal, opioid-sparing approaches for the management of

acute postoperative pain.^{20,25} ERAS protocols are being incorporated for both outpatient and inpatient surgical procedures. Acetaminophen and NSAIDs are frequently considered pharmacologic options within selected protocols.⁶⁴ Clinical studies and available resources can provide evidence-based data and meaningful information.

Patients must be aware of the risks and benefits of OTC analgesics and their role in managing pain. Providers, pharmacists, and other clinicians should not overlook the importance of pain education. For example, OTC product formulations offered through various routes of administration can contain

different amounts of acetaminophen and/or NSAIDs.⁶⁶ Frequently, patients are unaware of this, which may then complicate health issues through concomitant nonprescriptive or prescriptive medication(s) within their treatment plan. Verbal conversations, supplemented with written materials, provide patients with accurate and up-to-date information regarding efficacy, safety, dosing, storage/disposal, and selection of appropriate OTC analgesics.

Case Study: An Active 72-Year-Old Man Undergoing Total Hip Arthroplasty

The patient presented with a history of increasing left hip pain, limited mobility, and arthritic joint changes. Past treatment included a steroid injection under fluoroscopy into the left hip joint and aspiration of a large amount of fluid. He showed positive response for 2 months, until symptoms recurred despite physical therapy and other conservative treatment measures. Extra-strength acetaminophen 500 to 1,000 mg as needed (maximum daily dose not to exceed 3,000 mg),

physical therapy/conditioning, and other conservative measures were utilized until left total hip arthroplasty could occur.

An ERAS protocol, a multimodal, opioid-sparing approach with spinal anesthesia, was selected. Patient/caregiver education was utilized throughout the entire process. For acute postoperative pain, he was prescribed 5 mg of oxycodone and 1,000 mg of extra-strength acetaminophen during hospitalization. Following overnight hospitalization, the patient was discharged the next afternoon with no complications.

One week postoperatively, the patient was reported to be doing well at home and undergoing physical therapy. Oxycodone 5 mg orally was given 30 minutes prior to the first in-home physical therapy session. He experienced an uneventful recovery with return of normal bowel function and no opioid-induced constipation. Extra-strength acetaminophen (500-1,000 mg) was required only 1 to 2 times daily for adequate pain relief. Deep vein thrombosis prophylaxis, ice pack, physical therapy, and activities of daily living regimen continued. The patient progressed without complications, was compliant with the plan of care, and was pleased with the outcomes.

“So I Just Have to Live With This Pain Forever?”

Charles Vega, MD

A 58-year-old man presented for the second time for chronic low back pain, and was insistent on obtaining refills of oxycodone. I had reviewed his magnetic resonance imaging results and previous clinic notes and concluded that chronic opioid therapy was not the best treatment for his pain. He disagreed vociferously and became aggressive. People can be hurt or healed in these moments. I made a point not to match his emotion, but instead invited him to sit down and tell me his story. Like most patients, he simply wanted to reduce the pain to a level where he could work, play, and live like himself again. That gave us a starting point.

The starting point for this patient took us all the way back to the beginning. Unfortunately, a prescription for opioids had

been initiated at the onset of his treatment, skipping the stepwise process in the progression of pain management. We went back to trying physical therapy, mental health treatment, and low-risk OTC analgesics, such as acetaminophen.

This new plan required an investment from the patient as well as his entire health care team. It has not been easy, and the patient still has bad days. However, he is doing better than he was during that second visit to my clinic a year ago. His current treatment plan carries a low risk for developing serious AEs. Most importantly, he has been empowered in helping manage his own wellness and firmly believes in the plan of care. Together, we expect good things in the years to come.

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Disclosures: Dr Nalamachu reported that he is a consultant to and has received honoraria and speaking fees from Assertio, AstraZeneca, Daiichi Sankyo, Ferring, Janssen, Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare, Pernix Therapeutics, and Purdue, and owns stock in Scilex.

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