Why do we prescribe Vicodin?

Vicodin, a fixed-dose combination analgesic containing acetaminophen, or N-acetyl-p-aminophenol, (APAP) and hydrocodone, is the most frequently recommended opioid pain reliever prescribed by US oral surgeons after the extraction of third molars. It was first introduced to the US market in 1978, and today, APAP-hydrocodone combinations (for example, Vicodin, Norco, Lortab, and Zydone) have the dubious reputation of being our nation’s most frequently prescribed analgesics, as well as our nation’s most frequently abused prescription drugs. 

Surprisingly, we could find no references in the literature in which investigators found APAP-hydrocodone combinations, as currently prescribed and formulated, to be more effective than nonsteroidal anti-inflammatory drugs (NSAIDs).

The analgesic efficacy of even the most common over-the-counter NSAIDs such as ibuprofen and naproxen sodium first became recognized in the 1980s. Unlike APAP, NSAIDs are potent inhibitors of prostaglandin synthesis and target the inflammatory pain encountered with acute infection, tissue injury, and surgical trauma. Consequently, when treating inflammatory pain, NSAIDs consistently have been shown to be more effective than APAP. In 2015, investigators of 2 evidence-based Cochrane systematic reviews of oral analgesics assessed the efficacy and adverse effects of nearly all oral analgesic formulations. These comprehensive meta-analyses included results from 350 individual randomized clinical trials in which investigators assessed data in more than 45,000 participants undergoing both dental and medical surgical procedures. The findings of these and other comprehensive reviews unequivocally confirm 2 major conclusions: NSAIDs are remarkably effective analgesics for relieving postoperative pain, and the opioid analgesic combinations are associated with high incidences of adverse effects (nausea, vomiting, constipation, and so on). And of no less importance, relying on NSAID analgesics rather than opioid pain relievers does not add to our nation’s ongoing prescription opioid abuse epidemic.
So what compels us to prescribe Vicodin and the other APAP-opioid analgesic combinations? As health care providers, we have a primary responsibility to treat disease and manage pain effectively when they occur. Pain control is fundamental for compassionate patient care and successful practice. If NSAID analgesics are at least as effective as APAP-opioid pain relievers and have lower incidences of adverse effects, why do we prescribe APAP-opioid pain relievers for our patients?

ESTABLISHED PRESCRIBING BEHAVIORS
Continuing to provide practice-tested therapies that we were taught in professional school and specialty training is not uncommon for either dental or medical practitioners. We were instructed to prescribe APAP-opioid combinations such as Vicodin (or, for older dentists, Tylenol with codeine) routinely because these combination formulations were thought to be the most effective oral analgesics for managing acute postoperative pain. It is difficult to change traditional thinking and initiate alternative drug therapies that may involve acquiring new knowledge in pharmacology and therapeutics. As health care providers, our attitude is often to stay with what we know and trust. Although this attitude is not surprising, it is not always in the patient’s best interest.

Knowledge of the efficacy of APAP-opioids was established in the 1970s, nearly 10 years before the profound analgesic efficacy of NSAIDs was elucidated fully. After the introduction of Vicodin and other APAP-opioids, we entered an era of more sophisticated clinical research of analgesic medications. Over the past several decades, investigators have used appropriately controlled comparators and established acute pain models by conducting large multicenter randomized clinical trials. Comparisons between clinical trials, particularly with use of the well-accepted impacted third-molar extraction model, became possible. Advancements in our understanding of these effective non-opioid analgesics has been established and now can be used to improve patient care dramatically. Up-to-date knowledge of the efficacy and safety of the NSAID analgesics and their primary role for acute postoperative pain should be emphasized throughout a student’s dental school experience, as well as our professional continuing education programs.

THE IMAGE OF US DRUG ENFORCEMENT ADMINISTRATION CONTROLLED SUBSTANCES
When we prescribe opioid formulations, we understand that these agents are “strong” or “potent” and that they have significant abuse potential. This perception of strength was enhanced when the US Drug Enforcement Administration changed the classification of APAP-hydrocodone analgesics from schedule III to schedule II. Schedule II drugs are designated as having a higher abuse potential and include parenteral analgesics such as fentanyl, hydromorphone, and morphine. With this change, a patient is required to provide the pharmacist with a written or electronic prescription. Except in an emergency, a prescription order for a schedule II drug may not be called in to many pharmacies. Refills for schedule II prescription drugs also are prohibited. Despite the inconvenience of the schedule II regulations for both patients and practitioners, we continue to prescribe APAP-hydrocodone combinations partly because of familiarity and partly to avoid after-hours emergencies. These requirements only heighten our belief that these agents are truly effective.

ENHANCED PLACEBO RESPONSE
In the past 40 years, investigators in almost all clinical trials in which they have evaluated new analgesic medications have assessed analgesic efficacy compared with that of a placebo. Results from these studies consistently indicate that placebo pills are effective at least 10% to 20% of the time, particularly during the initial evaluation periods. The less severe the pain episode, the greater the placebo response. In clinical trials involving simple extractions, osteoarthritis, or muscle soreness, the placebo response is often greater than 40%. The pain relief that a patient experiences when taking an active analgesic is defined as the benefit of the active drug over and above the placebo response.

In clinical practice, prescription opioid formulations produce significantly enhanced placebo responses. With these prescription drugs, patients incur additional costs, the inconvenience of traveling to a pharmacy, and receipt of written and verbal precautions. Prescriptions are written using Latin abbreviations and are dispensed by a pharmacist, reinforcing the narrative supporting a patient’s belief that these agents are more effective than over-the-counter analgesics. The tablets dispensed by the pharmacist often have unique shapes and a mysterious code embossed on the side. Beyond the inert “sugar pill” used in clinical research studies, placebo responses in clinical practice include deep-seated beliefs and expectations that are ingrained in both patients and practitioners.

PRESCRIBING FOR THE MOST SEVERE OUTCOME
Most of our analgesic prescriptions are provided for management of postoperative pain. After various dental and oral surgical procedures, we make a decision to prescribe a specific analgesic agent, at a specific dose, and with a specific regimen. At the moment we make this decision, the patient is usually still numb and not in pain. We are making our best judgment of the patient’s needs on the basis of the length of the procedure and degree of surgical trauma. Given that we actually do not know how much pain a patient
will experience, we most often provide a prescription for an opioid analgesic sufficient to manage the worst case scenario—that is, those few patients who will have the most painful recovery.\(^8\) By writing a prescription that may benefit 20% of patients who will experience severe discomfort, we unnecessarily provide 80% of patients with a prescription they may not need. The dilemma is determining who will need an opioid analgesic and who will not. The inability to predict who may need an opioid analgesic after outpatient surgery is a problem for both medicine and dentistry. Patient education and counseling when providing an opioid prescription is necessary and has the potential to avoid unnecessarily filling an opioid analgesic prescription and possibly curtail its use when not absolutely required.

UNFOUNDED EXPECTATIONS OF APAP EFFICACY

When APAP is used in an opioid analgesic combination, we assume that it is formulated to optimize the analgesic benefit. However, because of concern for APAP-induced hepatic toxicity, the US Food and Drug Administration in 2013 requested pharmaceutical companies to limit the APAP dose in these combination formulations to 325 milligrams.\(^{19-21}\) This lowered APAP dose in opioid combinations reduces the potential for liver damage but also provides less analgesia than did the formulations that previously contained 500 or 750 mg of APAP. In clinical dental practice, prescriptions for Vicodin and Percocet most often are written for 16 to 24 tablets, with instructions to take 1 tablet every 4 to 6 hours, as needed, for pain.\(^{13,18,22,23}\) Consequently, the amount of the APAP in 1 tablet of a combination opioid analgesic is often suboptimal.

PATIENT EXPECTATIONS AND DEMANDS

After completing any surgical procedure, patients expect and deserve our best efforts to manage any pain experienced during their days of recovery at home. Because a patient expects to receive the most effective of pain relievers, dental and medical care practitioners often feel obligated to prescribe opioid combinations such as Vicodin or Percocet. If we prescribe or recommend a nonopioid, some patients may be dissatisfied and may consider the provider uncaring or unsympathetic. Effective pain management is, after all, the Holy Grail for achieving patient satisfaction.\(^{24}\)

Not providing an opioid prescription also can have significant consequences for today’s medical and dental practice models. Formal provider reviews conducted by corporate and hospital administrators can include poor ratings from patients who are disgruntled when they have not received their preferred opioid analgesic, even when it is not indicated. Because many dental and medical practices provide care in private settings, practitioners risk receiving critical postings on social media sites as well. These unwarranted reports are in the public domain and can result in loss of referrals from other patients and practitioners. We prescribe opioid analgesics to manage patients’ potentially severe postoperative pain, and at times we feel influenced to provide opioid analgesics to ensure patient satisfaction.

CHANGING STRATEGIES FOR POSTOPERATIVE PAIN MANAGEMENT

Because of the safety and efficacy of NSAID analgesics, unless contraindicated, they should continue to be our primary agents for managing postoperative pain. A prescription for an opioid combination analgesic after outpatient surgery may be needed for certain patients and after certain procedures; therefore, opioid pain relievers remain an essential part of a dentist’s therapeutic options. However, there are other effective strategies for postoperative pain management that do not require Vicodin and the other APAP-hydrocodone formulations. One effective alternative is the combination of APAP and ibuprofen.\(^{25-28}\)

If pain is severe and an opioid is deemed necessary, an analgesic combination containing an NSAID such as ibuprofen rather than APAP is likely to be more effective when appropriate.\(^{29}\) Multimodal perioperative pain management approaches that include preemptive NSAIDs to limit pain severity, long-acting local anesthetics to delay pain onset, and corticosteroids to limit postoperative inflammation and swelling may diminish or eliminate the need for opioid analgesics.\(^{30-32}\) Counseling patients about their anticipated postoperative pain experience and possible need for opioids must be provided as well.

Surgical extraction of third molars is an outpatient procedure provided to approximately 3.5 million young adults in the United States each year.\(^1\) This common procedure has provided a wealth of clinical and research evidence of oral analgesic efficacy. The use of APAP-hydrocodone analgesics after minor outpatient surgery performed in dentistry and in medicine have similar prescribing issues and non-pharmacologic reasons for their use.\(^{22,23}\) Many effective alternatives for managing postoperative pain that are opioid sparing are available. Clearly, it is time for all of us, both providers and patients, to reexamine our continued reliance on Vicodin to manage postoperative pain.

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