



May 22, 2020

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Re: Request for Comment, Docket No. CDC-2020-0029; [FR Doc. 2020-08127 Filed: 4/16/2020 8:45 am;
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On behalf of the more than 5,300 members of the American Society for Regional Anesthesia and Pain Medicine (ASRA), including solo practitioners, small group practice members, and practitioners in large private and academic healthcare systems, we thank you for the opportunity to comment on the management of acute and chronic pain.

Experiences managing pain, which might include the benefits, risks, and/or harms of the pain management options.

The decision to prescribe opioids or other pain medications should be based on a personalized medicine model, carefully considering the risks, benefits, alternatives, goals, expectations, and monitoring system for individual patients. Pragmatic approaches to evidence-based opioid prescribing seek to provide pain relief without adversely affecting patient outcomes.¹

Acute Pain: There is evidence that brief exposure to opioids, such as might occur during or after surgery, can induce tolerance and hyperalgesia.² Evidence from several large database studies demonstrates that patients undergoing surgery have an increased risk of persistent opioid use months later, which for some surgeries and patients can be as high as a 15-fold increase in risk.³ Whether reducing perioperative opioids can reduce the risk of persistent opioid use remains unknown. Randomized, controlled trials that specifically address this topic are lacking but are needed. Observational studies have found that some interventions, such as peripheral nerve blockade, have no association with the risk of persistent opioid use after several surgery types.⁴

Chronic Pain: As a leading cause of disability in the U.S. and worldwide, chronic pain is associated with multiple psychiatric morbidities including depression and anxiety, and even controlling for the higher risk of overdose and suicide, is associated with decreased life expectancy.⁵ Unfortunately, non-opioid treatments for chronic pain, including injections, surgery and integrative treatments, typically provide < 50% pain relief for less than half the population.⁶ By some metrics, opioids are the most effective treatment for acute pain, and possibly for chronic pain. Although there are no placebo-controlled studies showing opioids are efficacious beyond 16 weeks, there are data suggesting improvement in function and quality of life that extend beyond 1 year.⁷ Similarly, there are also no placebo-controlled trials showing non-opioid medications are efficacious beyond 12-16 weeks.

Opioids contain significant risks and side effects, and should not be a first-line treatment for chronic pain. However, in carefully selected patients, the incidence of addiction is < 8%.⁸ If opioids are prescribed, there should be a clearly delineated exit strategy.⁹



Experiences choosing among the pain management options, including considering factors such as each option's accessibility, cost, benefits, and/or risks.

Acute Pain: Multimodal analgesia, which is the simultaneous use of analgesics with more than one mechanism of action, improves perioperative pain and reduces perioperative opioid use after many surgeries. Opioid-free anesthesia during surgery has been studied in several small trials and multiple observational studies,^{10,11,12} and may reduce opioid-related side effects while possibly providing similar analgesia.¹³ However, it is not yet clear that opioid-free anesthesia has an effect on persistent opioid use.

Although opioid-free anesthesia can reduce the amount of opioids used in the days following surgery, the practice has not yet affected opioid prescribing habits, which may require better education and easier implementation. It is unlikely that long-term outcomes will be affected without changes in both perioperative pain management and prescribing behavior.

Intravenous ketamine¹⁴ and lidocaine¹⁵ infusions are two potent analgesic alternatives to opioids. Both can reduce opioid use for hospitalized patients undergoing a variety of surgeries but should be tailored to patients most likely to benefit, such as those who are opioid tolerant or undergoing painful procedures such as major gastrointestinal surgery, fusion surgery or thoracotomy. Although these strategies could theoretically lead to long-term reductions in opioid use, this has not been proven in clinical studies.

Acute Pain in Patients with Opioid Use Disorder: Management of acute pain, including postoperative pain, may be more challenging in patients with opioid use disorder, including those in medication-assisted therapy. As with acute pain management in other groups, non-opioid analgesics should be used whenever possible, including intravenous infusions such as ketamine and lidocaine if permitted by local hospital or clinic policies. Neuraxial and peripheral nerve blockade should also be considered, if appropriate, for surgical patients. Expectations should be discussed with patients prior to treatment and it should be emphasized that complete relief of pain is unlikely.

Daily assessment in the hospital with a validated tool such as the Clinical Opiate Withdrawal Scale may help to provide objective evidence of the severity of withdrawal. The decision of whether to continue medication-assisted therapy (buprenorphine, methadone, or naltrexone) through the perioperative period should ideally be made by a multidisciplinary team involving the patient's outpatient prescriber, the surgeon, and an anesthesiologist. Methadone should be continued in the hospital after confirmation of the patient's outpatient dose. Practice advisories and expert consensus panels are increasingly recommending continuation of buprenorphine in the perioperative period to minimize risk of relapse, although randomized, controlled trials comparing approaches have not been performed.

Perioperative management of patients taking oral or long-acting intramuscular (IM) naltrexone is not well described. Analgesia may be more difficult to achieve and non-opioid analgesics should be used whenever possible. Full mu-opioid agonists may need to be given in higher doses if used, although evidence for this is lacking. Case reports describe a lack of analgesia in patients given full mu-opioid agonists during the first 2 weeks after IM naltrexone administration.^{16,17} A discussion of the risks and benefits of surgery should take place if regional anesthesia and multimodal analgesia are not possible.



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A short course of the lowest effective dose of short-acting opioids should be used if needed for acute pain refractory to non-opioid analgesics.⁸ For patients already taking buprenorphine, a total daily sublingual dose of 16 mg is associated with greater than 85% mu-receptor occupancy.¹⁸ Existing evidence suggests that continuation of buprenorphine throughout the perioperative period can be done in patients with total daily doses of 16 mg and greater while still achieving adequate analgesia.¹⁹ Post-discharge follow-up should be discussed during hospitalization and consideration of consultation with experts in substance use disorder should be given.

Concerns Regarding Suboptimal Pain Management: The well-publicized side effects of opioids may overshadow the consequences of severely restricting their use for appropriately selected patients and approved indications. These include: patients whose pain goes untreated or are abandoned by physicians who refuse to write or taper opioid prescriptions; arbitrary restrictions by insurance companies on the type and doses of opioids prescribed; and restrictions on the use or access to buprenorphine.

In addition, a lack of access to providers with training in pain medicine prevents many patients from achieving optimal pain management. Moreover, many physicians decline to write opioid prescriptions, which has led to an unreasonable expectation by providers and patients that pain medicine physicians should write all opioid prescriptions. There is also a lack of insurance reimbursement/coverage for mental health services, and increasing restrictions on performing procedures, to support patients seeking treatment for their pain.

Experiences getting information needed to make pain management decisions.

The “opioid epidemic,” widely covered in the mass media, has made patients more aware of pain medication risks, and physicians more cognizant of opioid use and dosing. The challenge is to balance the needs of patients in pain against the regulatory burdens, without abandoning patients or ignoring the potential risk of pain medication diversion and abuse.

As anesthesiologists, and acute and chronic pain medicine specialists, ASRA members are constantly reviewing and sharing with peers the evidence regarding optimal pain management. The same evidence informs our discussions with patients in pain, who need “to be aware that the use of [pain] drugs is not an inalienable right, but rather an ongoing trial whereby pain relief, functional improvement and mood enhancement are continuously balanced against side effects...”⁹

To that end, ASRA provides authoritative resources for both patients and physicians at:
<https://www.asra.com/>

Sincerely,

Eugene R. Viscusi, MD
President, ASRA



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