Neurology and Pain Management

Compassionate Medicine for the 21st century

Our approach to opioid prescription practice May 2016

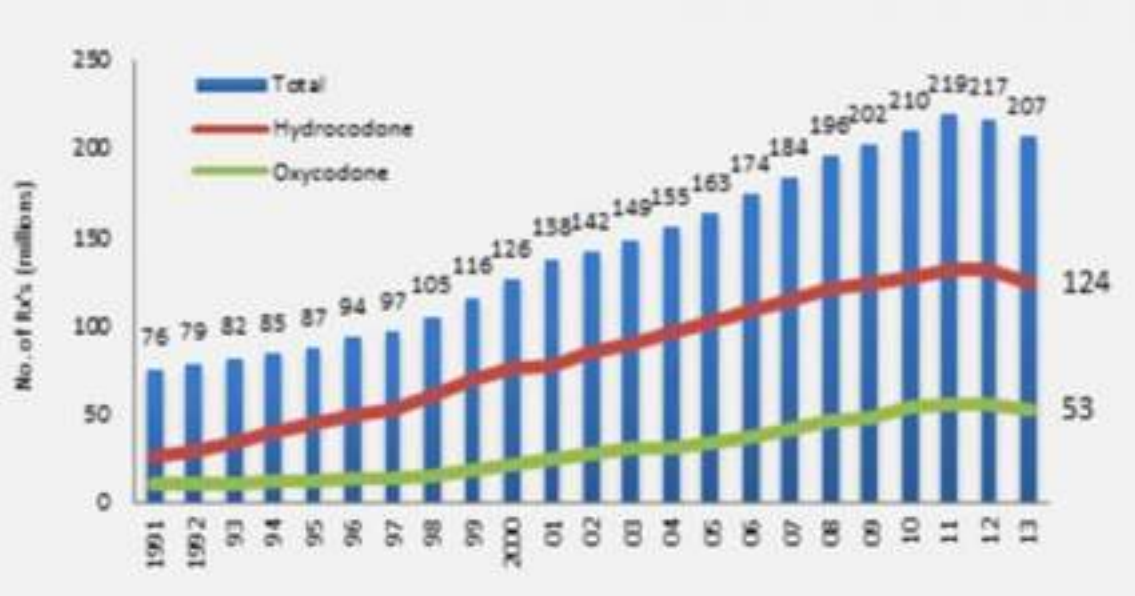
BACKGROUND

The abuse of and addiction to opioids such as heroin, morphine, and prescription pain relievers is a serious global problem that affects the health, social, and economic welfare of all societies. It is estimated that between 26.4 million and 36 million people abuse opioids worldwide,[1] with an estimated 2.1 million people in the United States suffering from substance use disorders related to prescription opioid pain relievers in 2012 and an estimated 467,000 addicted to heroin.[2] The consequences of this abuse have been devastating and are on the rise. For example, the number of unintentional overdose deaths from prescription pain relievers has soared in the United States, more than quadrupling since 1999. There is also growing evidence to suggest a relationship between increased non-medical use of opioid analgesics and heroin abuse in the United States.[3]

[1] UNODC, World Drug Report 2012. http://www.unodc.org/unodc/en/data-and-analysis/WDR-2012.html

[2] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[3] Pradip et al. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the US. Center for behavioral Health Statistics and Quality Data Review. SAMHSA (2013)http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.htm



The total number of opioid pain relievers prescribed in the United States has skyrocketed in the past 25 years (see graph above),[4] The number of prescriptions for opioids (like hydrocodone and oxycodone products) have escalated from around 76 million in 1991 to nearly 207 million in 2013, with the United States their biggest consumer globally, accounting for almost 100 percent of the world total for hydrocodone (*e.g.,* Vicodin) and 81 percent for oxycodone (*e.g.,* Percocet).[5]

In terms of abuse and mortality, opioids account for the greatest proportion of the prescription drug abuse problem. Deaths related to prescription opioids began rising in the early part of the 21st century. By 2002, death certificates listed opioid analgesic poisoning as a cause of death more commonly than heroin or cocaine.[6]

It is estimated that more than 100 million people suffer from chronic pain in this country.[7] and for some of them, opioid therapy may be appropriate. The bulk of American patients who need relief from persistent, moderate-to-severe non-cancer pain have back pain conditions (approximately 38 million) or osteoarthritis (approximately 17 million).[8] Even if a small percentage of this group develops substance use disorders (a

[4] IMS's National Prescription Audit (NPA) & Vector One ®: National (VONA).

[5] International Narcotics Control Board Report 2008.. United Nations Pubns. 2009. p. 20

[6] Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. REPORT BRIEF JUNE 2011; Johannes et al. The prevalence of chronic pain in United States adults: results of an Internet-based survey. J Pain. 11(11):1230-9. (2010); Gallup-Healthways Well-Being Index.

[7] Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. REPORT BRIEF JUNE 2011; Johannes et al. The prevalence of chronic pain in United States adults: results of an Internet-based survey. J Pain. 11(11):1230-9. (2010); Gallup-Healthways Well-Being Index.

[8] De Leon Casada. Opioids for Chronic Pain: New Evidence, New Strategies, Safe Prescribing The American Journal of Medicine, 126(3s1):S3–S11. (2013)

subset of those already vulnerable to developing tolerance and/or clinically manageable physical dependence), a large number of people could be affected.

Scientists debate the appropriateness of chronic opioid use for these conditions in light of the fact that long-term studies demonstrating that the benefits outweigh the risks have not been conducted. In June 2012, NIH and FDA held a joint meeting on this topic, and now FDA is requiring companies who manufacture long-acting and extended-release opioid formulations to conduct post-marketing research on their safety.[9]

Recently Johns Hopkins medical center published an evidenced based approach to prescriptions drugs[10] and Katz et.al, have identified the so called stakeholders in the management of risk in prescribing opioids.[11]

Our Approach[12]

1. **Use the same process (identify pain syndrome, discuss risks and benefits) every time we prescribe opioids for chronic pain. This is done monthly for most patients and bimonthly for "trusted" patients.**
2. **Perform imaging studies including CT and MRI as well as electrophysiological studies such as EMG, NCV and SSEP to confirm pathology and ongoing nature of cause for pain.**
3. **Assess risks for misuse by the use of the SOAPP system[13].**
4. **Use a pain management treatment contract/agreement.**
5. **Identify an appropriate formulary for our practice. (We avoid for instance the use of OxyContin and long acting delivery systems because of the relative risk of these drugs).**
6. **Integrate urine toxicology screens into our prescribing patterns**

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[9] for more see:
http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf

[10] http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf

[11] Increased abuse and diversion of prescription opioids has been a consequence of the increased availability of opioids to address the widespread problem of undertreated pain. Opioid risk management refers to the effort to minimize harms associated with opioid therapy while maintaining appropriate access to therapy. Management of these linked public health issues requires a coordinated and balanced effort among a disparate group of stakeholders at the federal, state, industry, practitioner, and patient levels. This paper reviews the principles of opioid risk management by examining the epidemiology of prescription opioid abuse in the United States; identifying key stakeholders involved in opioid risk management and their responsibilities for managing or monitoring opioid abuse and diversion; and summarizing the mechanisms currently used to monitor and address prescription opioid abuse. Limitations of current approaches, and emerging directions in opioid risk management, are also presented.

See Katz, Nathaniel P. MD, MS et al. Foundations of Opioid Risk Management: Clinical Journal of Pain: February 2007 - Volume 23 - Issue 2 - pp 103-118

[12] We use the recommendations from 'Best Practice Guidelines' by Gardner et al…
https://www.acponline.org/system/files/documents/about_acp/chapters/ri/14mtg/opioid1.pdf

[13] https://nhms.org/sites/default/files/Pdfs/SOAPP-14.pdf

Our Philosophy

Our practice is based on compassionate medicine and our goal is to provide neurological care and chronic pain management using the highest ethical standards of care. Our guidelines balance the need to care for our patients with the need to "protect the public trust" and to follow the Hippocratic oath of "DO NO HARM".
We realize the benefit of short term relief of pain and the need to balance it with the long term harmful effects of opiate use. (The physiologic consequences of opioid use are adverse, occur quickly, and can be permanent. Decreased brain gray matter, release of calcitonin gene-related peptide, dynorphin, and pro-inflammatory peptides, and activation of excitatory glutamate receptors are all associated with opioid exposure).

We therefore attempt to use the minimal amount and dosage of opiate drug needed to manage unbearable pain and combine its use with anti-inflammatory drugs, physical therapy and injections.

Many patients come to us on massive doses of opiates prescribed by general practitioners of other pain management clinics. We need to then re-educate them as to our philosophy of practice which often causes anxiety that we will "cold turkey" them off all medications. Nothing could be further from the truth. The doctor patient relationship demands compassion above all other concerns, however we will be certainly titrating them down off the massive doses they come to us on, if we feel there is an inappropriate prescription of opiates by other prescribers. We approach this carefully by combining the appropriate use of opiate dosage with judicious use of injections and therapy as well as other anti-spasm and anti-inflammatory medications.

We engage in strategies to identify risk patients in order to protect the public trust by the use of the State prescription on line "Inspect" reports as well as the urine toxicology screens. These identify aberrant behaviors as well as "doctor shoppers" and have protected our legitimate patients who seek pain relief. The SOAPP forms are to be filled out at every visit and identify risk behaviors. We therefore stratify risk at 4 levels based on the risk of diversion, aberrant behavior and use of concurrent illegal drugs. These risk assessments protect our licensure as well as the public trust.

We choose medications based on evidenced based medicine principles.[14] The use of opioids is usually accompanied by muscles relaxants (flexeril, zanaflex, and baclofen) especially for axial spine pain where muscles spasm is a large component of the pain syndrome. For neuropathic pain due to diabetes and other causes we use such agents as Neurontin and Lyrica. For the pain

[14] for instance the choice between hydrocodone and oxycodone see http://www.healthline.com/health/pain-relief/vicodin-vs-percocet#Choosing5

of central causes such as Multiple Sclerosis, RSD or post stroke pain we are challenged by the refractory nature of such pain.

Many times we identify anxiety as a co-morbidity in pain syndromes. Patients often mis-identify depression and anxiety disorders as pain. Unfortunately, many of our patients cannot afford the luxury of psychological care and come to us with multiple life complaints of which chronic physical pain is only one component. We have a responsibility to accurately define the cause of pain and treat the appropriate causes. This is why we perform imaging and electrical studies, as well as blood studies. We routinely find diagnoses that were missed by other referring physicians (in a study in 2013 we found a 15% rate of misdiagnosis of patients referred to our clinic.)[15]

Many patients come to us with a diagnosis of **fibromyalgia** of which prior sexual and other abuse has a high degree of correlation.[16] Merely treating the pain symptoms surely does not get to the heart of the cause yet because of the socio-economic realities of our population we seem to be the only access to healthcare (be it because of limited funds to travel to clinics or other medical reasons) yet we have to address these issues. Furthermore, we have found missed diagnoses such as neuropathy, discogenic disease, polyarthritis and Lupus, sarcoid in many patients who have been "written off" as fibromyalgics. The FDA treatment for fibromyalgia allows for 3 approved drugs *none of which are opiates*. This is a big challenge for those patients who cannot tolerate Lyrica, Savella, or Cymbalta because of side effects.

Migraine is another disease we treat that proves a big challenge. The use of opiates is not recommended for the treatment of migraine disorders.[17] Yet many patients are referred to us after the primary care physician throws up his hands after having tried the usual pharmacy of medications approved for migraine. Again the psychological co-morbidities and triggers are usually uncovered after listening to the patient carefully and often can be avoided. Yet we have a persistent core of patients who come to us opiate dependent. We advocate the weaning off these medications and the judicious use of BoTox injections[18] and deep tissue massage therapy in combination with new FDA approved drugs.[19]

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[15] QI study for AAAHC certification 2013

[16] http://www.ncbi.nlm.nih.gov/pubmed/7848314

[17] http://www.ncbi.nlm.nih.gov/pubmed/22540203

"Opioids should not be used for the treatment of migraine. Alternative acute and preventive agents should always be explored. Opioids do not work well clinically in migraine. No randomized controlled study shows pain-free results with opioids in the treatment of migraine. Saper and colleagues' 5-year study showed minimal effectiveness, with many contract violations, interfering with the therapeutic alliance. The physiologic consequences of opioid use are adverse, occur quickly, and can be permanent. Decreased gray matter, release of calcitonin gene-related peptide, dynorphin, and pro-inflammatory peptides, and activation of excitatory glutamate receptors are all associated with opioid exposure. Opioids are pro-nociceptive, prevent reversal of migraine central sensitization, and interfere with triptan effectiveness. Opioids precipitate bad clinical outcomes, especially transformation to daily headache. They cause disease progression, comorbidity, and excessive health care consumption. Use of opioids in migraine is pennywise and pound foolish."

[18] http://www.ncbi.nlm.nih.gov/pubmed/10849039 for an evidence based study.

[19] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm414707.htm

The use of injections (from local nerve blocks to epidurals, pain pumps and dorsal column stimulators) is an integral part of our pain management program.

We believe that a combined approach making use of all these parameters significantly manages moderate to severe pain in our population of patients.

For further questions please feel free to contact us at jyungar@mac.com

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