REPORT

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ORIGINATION AND PURPOSE OF ULTRA HIGH POTENCY, SUBCUTANEOUS HYDROMOPHONE

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I recall the time, about 2010-2012, when Anazao Laboratory in Tampa, Florida informed me they had developed ultra-high potency (50 mg/ml) hydromorphone for palliative pain care. In contrast to the other injectable opioids, this formulation could be injected subcutaneously rather than intramuscularly. The injection required a very small amount of fluid (i.e., .1 to .2 ml) by use of an allergy or insulin syringe.

Anazao Labs was aware of my patient needs since they formulated my endocrine medicinals. My patients were called "intractable" to meet California's Medical Board and legal definitions. Criteria to enter the clinic was a determination that terminus was a high risk within one year unless opioid treatment could be administered. All patients met this definition of legitimate pain: "A stressful symptom caused by a disease or injury that can be objectively identified by diagnostic tests or physical examination." Top causes of intractable pain were adhesive arachnoiditis, traumatic brain injury, severe neuropathies (CRPS), autoimmune disease, and post-cancer.

I recall the first patient to whom I prescribed ultra-high potency hydromorphone. She was not receiving adequate pain relief with both a long-acting and breakthrough opioid, so she was referred for an intrathecal implanted device for opioid administration. Due primarily for insurance reasons, she could not obtain this expensive treatment, so I chose to experiment with the new ultra-high potency hydromorphone. It worked remarkably well. In fact, she soon found she didn't require both her long-acting and breakthrough opioid, and by use of the new hydromorphone formulation she dropped her daily morphine equivalence dosage from over 500 to less than 100 mg per day.

After success with this patient, I prescribed ultra-high dose hydromorphone to patients on high dose oral opioids who could not obtain intrathecal opioids or an implanted electrical stimulator. All the patients tolerated and adjusted well to high potency hydromorphone. Consequently, ultra-high dose hydromorphone became an alternative to intrathecal opioids. Today this remains a major reason for ultra-high potency hydromorphone. My initial experience told me that ultra-high potency hydromorphone may be an alternative to standard intractable pain care which is the combined use of a long-acting opioid with a short-acting opioid for breakthrough pain. This therapy has short comings in that long-acting opioids suppress endocrine levels. I began to prescribe ultra-high potency hydromorphone to some of these patients. I found that I could eliminate or reduce high dose opioid administration of oral, patch, or sublingual route administration with the ultra-high potency hydromorphone and obtain equal or superior pain relief.

My procedure in prescribing hydromorphone was to instruct both the patient and a live-in family member on sterile measures, injection technique, and secure storage. At the time I closed my clinic, I probably had about 2 dozen patients who successfully used this innovative formulation.

I made some observations and have come to some conclusions that somewhat go against common beliefs about opioid therapy. First and foremost, high potency hydromorphone can usually substitute in most cases for long-acting opioids such as Oxycontin®, fentanyl transdermal, and methadone. Effective pain relief occurs within minutes after the injection, so the patient doesn't have a proclivity to follow the opioid dose with a sedative/neuropathic drug

such as a benzodiazepine. Seldom does the patient use over 3 to 4 injections a day. To date, I know of no overdoses with this medicinal. I attribute this to its rapid, potent, short-acting activity that doesn't invite the use of other drugs (including alcohol), to help the patient achieve pain relief. Blood levels of the hydromorphone don't stay elevated longer than about two hours which protects against overdose. Pain relief remains much longer, however, likely because it is hydrophilic in neurologic tissues.

In summary, I have found ultra-high potency hydromorphone to be a significant advance in palliative pain care for intractable pain patients. It has proven to be a bonafide alternative to intrathecal opioid delivery and the high opioid dosages necessary with combined use of long and short acting opioids. Its unique properties seem to prevent overdoses. Families and patients can be trained to safely and effectively use this medicinal to relieve the suffering of the most severe forms of intractable pain. At this time, it is an under recognized and underused treatment for palliative care of intractable pain patients.