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Studies Show Marijuana Can Be an Effective Medicine for Pain

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Center for Medicinal Cannabis Research, "Report to the Legislature and Governor of the State of California Presenting Findings Pursuant to SB847 Which Created the CMCR and Provided State Funding," University of California, February 11, 2010, pp. 8-12, 16. Courtesy of the Center for Medicinal Cannabis Research.

The Center for Medicinal Cannabis Research conducts scientific studies intended to determine the general medical safety and efficacy of marijuana products.

Chronic pain—pain on a daily or almost daily basis for six months or longer—is one of the most prevalent and disabling conditions in California and in the US generally. Whereas many types of pain are caused by stimulation of specialized pain receptors on nerve endings due to injury of tissues, neuropathic pain is produced either by direct damage to the central (brain, spinal cord) or peripheral nervous system itself, or by abnormal functioning of these systems. Infections, diabetes, physical trauma, strokes, and many other diseases can injure the nervous system, with resulting pain, which persists even though pain receptors themselves are not directly activated. It is therefore not surprising that neuropathic pain is widespread, affecting 5-10% of the US population. Only a few classes of medications are approved for use as analgesics in these conditions (opioids, anticonvulsants, antidepressants), and many patients obtain only partial relief, even when using combinations of all available therapies. Among the most difficult to treat neuropathic pain conditions are those secondary to HIV, diabetes, and to physical trauma to the nervous system. Because these neuropathic disorders are so prevalent, and treatment alternatives are so limited, the CMCR [Center for Medical Cannabis Research] focused on these conditions.

Research on Marijuana for Pain

A distinguishing scientific feature of the program of pain research, made possible only by the coordinating function of the CMCR, is the commonality of measures and methods across the research studies. This allows for the distinctive advantage of comparability of results across studies. Additionally, when possible we studied treatment of the same type of pain condition (e.g., HIV neuropathy) in more than one geographic site. Finding comparable results at two or more sites studying the same disease is scientifically important, since this suggests that the results are generally valid, rather than being due to chance or the specific characteristics of a single sample of patients, or of a particular team of researchers.

This research used the gold standard design for assessment of therapeutic effects, the randomized clinical trial. In this approach participants are assigned by chance, like flipping a coin, to an experimental treatment, in this case cannabis, or to a placebo (an inactive treatment). The placebo in all of our studies was a marijuana (cannabis) cigarette, made with cannabis from which the "active" ingredients, for example delta-9-tetrahydrocannabinol (THC), had been removed. The cigarette therefore had the appearance and the aroma of a marijuana cigarette, but without the crucial chemical ingredients hypothesized to be therapeutically active. Randomization ensures factors which might skew the results (like age, duration or intensity of pain) are equally present in both the experimental and placebo condition. Placebo is essential, since the expectation of pain relief from any treatment is a powerful analgesic itself. All of our protocols used measures of pain recommended by expert consensus as standard in the field. For studies of smoked cannabis, the researchers used a standard, timed method of inhalation; research using vaporized cannabis used similar, state-of-the art technology. Researchers measured blood concentrations of the primary active ingredient of cannabis (THC), allowing estimates of relationships between dose, concentration, and magnitude of pain relief.

Results of Recent Studies

To date, the CMCR has completed four studies in the treatment of neuropathic pain. Two studies have focused on neuropathic pain resulting from HIV infection or the drugs used to treat HIV, one has focused on neuropathic pain of varying causes, and one has used an experimental model of neuropathic pain tested in healthy volunteers. The results from these four studies have been convergent, with all four demonstrating a significant decrease in pain after cannabis administration. The magnitude of effect in these studies, expressed as the number of patients needed to treat to produce one positive outcome, was comparable to current therapies. Two additional studies involving neuropathic pain are under way.

Multiple sclerosis (MS) is one of the most common chronic and disabling diseases of the nervous system. Caused by loss of the insulating sheath surrounding nerve fibers, the disease usually begins in young adulthood. Although it may initially wax and wane in intensity and be of mild severity, it often steadily progresses, causing fatigue, loss of balance, muscle weakness, and muscle spasticity. Affecting up to 70% of people with the disease, muscle spasms lead to pain, inability to walk, and difficulties with self-care, causing most of the everyday life disability from this disease. There is as yet no cure for MS. Treatments for muscle spasticity are only partially effective and have side effects which are not easily tolerated, making the search for new therapies of high importance. Given this background, the CMCR identified MS spasticity as an additional target for therapeutic research. As with all CMCR studies, the research used the most rigorous scientific approach to testing therapies, a randomized clinical trial, supplemented by modern measurement of muscle spasticity, everyday function, life quality, and side effects. Results to date have found a significant improvement in both an objective measure of spasticity and pain intensity in patients whose standard therapy had provided inadequate relief.

Medical Marijuana for HIV-Related Neuropathic Pain

The primary objective of this study ["The Effect of Cannabis on Neuropathic Pain in HIV-Related Peripheral Neuropathy"] was to evaluate the efficacy of smoked cannabis when used as an analgesic in persons with neuropathic pain from HIV-associated distal sensory polyneuropathy (DSPN). In a double-blind, randomized, five-day clinical trial patients received either smoked cannabis or placebo cannabis cigarettes. Patients continued on any concurrent analgesic medications (e.g., gabapentin, amitriptyline, narcotics, NSAIDs [nonsteroidal anti-inflammatory drugs]) which they were prescribed prior to the trial; the dose and amount of the medications were recorded daily.

The full results of this study appear in the journal *Neurology*. In brief, 55 patients were randomized and 50 completed the entire trial. Smoked cannabis reduced daily pain by 34% compared to 17% with placebo. The study concluded that a significantly greater proportion of patients who smoked cannabis (52%) had a greater than 30% reduction in pain intensity compared to only 24% in the placebo group. This result is clinically important, since the threshold of a 30% reduction in pain intensity is associated with meaningful improvement in quality of life in other research on pain outcomes.

Cannabis appeared to be well tolerated and there were no safety concerns raised. By design, all patients had smoking experience with cannabis. There were more side effects in those receiving cannabis than placebo, with the most frequent being sedation, anxiety, and dizziness, but these were all rated as "mild."

Medical Marijuana for Painful HIV Neuropathy

The primary objective of this study ["Placebo-Controlled, Double Blind Trial of Medicinal Cannabis in Painful HIV Neuropathy"] also was to evaluate the efficacy of smoked cannabis when used as an analgesic in persons with HIV-associated painful neuropathy. In a double-blind, randomized, clinical trial of the short-term adjunctive treatment of neuropathic pain in HIV-associated distal sensory polyneuropathy, participants received either smoked cannabis or placebo cannabis cigarettes. A structured dose escalation-titration protocol was used to find an individualized, effective, safe, and well-tolerated dose for each subject. Participants continued on their usual analgesic medications throughout the trial, with the dose and amount of these medications being recorded daily.

The full results of this study were published in the journal *Neuropsychopharmacology*. In brief, 34 eligible subjects enrolled and 28 completed both cannabis and placebo treatments. Among completers, pain relief was significantly greater with cannabis than placebo. The proportion of subjects achieving at least 30% pain relief was again significantly greater with cannabis (46%) compared to placebo (18%). It was concluded that smoked cannabis was generally well tolerated and effective when added to concomitant analgesic therapy in patients with medically refractory pain due to HIV-associated neuropathy. Once again these results appeared to be relevant to everyday clinical practice, because the magnitude of pain relief is associated with that which improves life quality, and also because the benefit was above and beyond that conferred by the patients' usual analgesics.

Both low and high cannabis doses were efficacious in reducing neuropathic pain of diverse causes.

As in the study described above, side effects were more frequent with cannabis than with placebo, with the most common being sleepiness or sedation, fatigue, and difficulty with concentration. These were "mild" for the most part and did not raise safety concerns.

Medical Marijuana for a Variety of Neuropathic Pain

This study's objective ["A Double-Blind, Placebo-Controlled Crossover Trial of the Antinociceptive Effects of Smoked Marijuana on Subjects with Neuropathic Pain"] was to examine the efficacy of two doses of smoked cannabis on pain in persons with neuropathic pain of different origins (e.g., physical trauma to nerve bundles, spinal cord injury, multiple sclerosis, diabetes). In a double-blind, randomized clinical trial participants received either low-dose, high-dose, or placebo cannabis cigarettes. As customary in CMCR

trials, participants were allowed to continue their usual regimen of pain medications (e.g., codeine, morphine, and others).

The full results of this study have been published in the *Journal of Pain*. Thirty-eight patients underwent a standardized procedure for smoking either high-dose (7%), low-dose (3.5%), or placebo cannabis; of these, 32 completed all three smoking sessions. The study demonstrated an analgesic response to smoking cannabis with no significant difference between the low- and high-dose cigarettes. The study concluded that both low and high cannabis doses were efficacious in reducing neuropathic pain of diverse causes.

Disagreeable or unpleasant side effects were significantly more likely with high-dose cigarettes compared to low-dose or placebo, whereas there was no difference in these effects between low-dose and placebo sessions. There was no indication of mood changes (e.g., sadness, anxiety, fearfulness).

Marijuana as Analgesic, or Pain Reliever

This study ["Analgesic Efficacy of Smoked Cannabis"] used an experimental model of neuropathic pain to determine whether pain induced by the injection into the skin of capsaicin, a compound which is the "hot" ingredient in chili peppers, could be alleviated by smoked cannabis. Another aim of the study was to examine the effects of "dose" of cannabis, and the time course of pain relief. In a randomized double-blinded, placebo-controlled trial, volunteers smoked low, medium, and high dose cannabis (2%, 4%, 8% THC by weight) or placebo cigarettes.

Smoked cannabis was superior to placebo in reducing neuropathic pain of diverse causes.

The full results of this study were published in the journal *Anesthesiology*. Nineteen healthy volunteers were enrolled, and 15 completed all four smoking sessions. In brief, five minutes after cannabis exposure, there was no effect on capsaicin-induced pain at any dose. By 45 minutes after cannabis exposure there was a significant decrease in capsaicin-induced pain with the medium dose (4%) and a significant increase in pain with the high dose (8%). There was no significant effect seen with low dose (2%). There was a significant inverse relationship between pain perception and plasma THC. In summary, this study suggested that there may be a "therapeutic window" (or optimal dose) for smoked cannabis: low doses were not effective; medium doses decreased pain; and higher doses actually increased pain. These results suggest the mechanism(s) of cannabinoid analgesia are complex, in some ways like non-opioid pain relievers (e.g., aspirin, ibuprofen) and in others like opioids (e.g., morphine).

Marijuana for Spasticity in Multiple Sclerosis

The objective of this study ["Short-Term Effects of Cannabis Therapy on Spasticity in Multiple Sclerosis"] was to determine the potential for smoked cannabis to ameliorate marked muscle spasticity (chronic painful contraction of muscles), a severe and disabling symptom of multiple sclerosis. In a placebo-controlled, randomized clinical trial spasticity and global functioning was examined before and after treatment with smoked cannabis. Patients were allowed to continue their usual treatments for spasticity and pain while participating in the research.

The full results of this study are being submitted for publication. Initial results were presented at the meeting of the American College of Neuropsychopharmacology in 2007. Thirty patients with multiple sclerosis were enrolled. Compared to placebo cigarettes, cannabis was found to significantly reduce both an objective measure of spasticity and pain intensity. This study concluded that smoked cannabis was superior to placebo in reducing spasticity and pain in patients with multiple sclerosis, and provided some benefit beyond currently prescribed treatments....

Results of CMCR studies support the likelihood that cannabis may represent a possible adjunctive avenue of treatment for certain difficult-to-treat conditions like neuropathic pain and spasticity.

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