

Side Effect Profile of Oral CBD Capsules in a Pain Management Population, 10-month Data Set

J.Julian Grove M.D., Peter K. Kubitz D.O. – Pain Consultants of Arizona, Phoenix AZ

PURPOSE

The purpose of this study was to evaluate all patients side effects who have chosen to take oral CBD capsules as a means for pain relief at our pain management center.

INTRODUCTION

The vast majority of pain medications that are at the disposal of health care providers that treat pain have potentially significant cognitive effects. Those that do not, often have end organ system damage including over the counter pain medications including NSAID (GI and Renal) and Acetaminophen (Liver). Separately, the ripple effects of the opioid crisis have highlighted the behavioral side effects that can ultimately be fatal as well.

In light of the multitude of side effects that pain physicians have to evaluate (opioids, neuropathic agents, skeletal muscle relaxants, NSAID), the authors wanted to evaluate a 10 month data set using specific CBD cream and specific oral CBD capsules ranging from 12.5 mg per day to 100 mg per day (in QD to BID dosing).

We have seen anecdotal data regarding side effects of tinctures of CBD and wanted to evaluate the side effect profile of oral CBD capsules and cream with a 10-month self-reported data set to evaluate CBD risk and benefit profile to a better degree. We feel that the better the understanding of the side effect profile of CBD, the better health care providers can make informed decisions regarding this as a potential recommendation as the use of CBD for pain complaints is better researched and more clinically used.

TYPE OF CBD

This was a specific, full spectrum CBD cream and specific capsules with supplementation for inflammation (Turmeric, Ginger, Piperine), nerve pain (alpha lipoic acid, Vitamin B12), headache (coenzyme Q10, Riboflavin, Magnesium), and sleep (Melatonin, Vitamin D).

MATERIALS AND METHODS

Patients reported side effects upon follow up, on a questionnaire at our pain management clinic. Those that were taking CBD followed up at a 1-3 month interval depending on other medications that they were taking and/or followed up by phone questionnaire.

Side effects for patients that were taking multiple medications were noted and only those side effects where each of the other medications were stable were attributed to the cannabidiol product.

We limited our data set to one type of cannabidiol brand to eliminate the wide variability and purity that exists in the cannabidiol landscape.

RESULTS

Overall, we saw a limited number of side effects, all less than 1% of our tested subjects. N=812 total.

The two cases of Maculopapular rash were seen with the CBD Cream, all other side effects were attributed to the capsules.

- Generalized Headache: 4 cases (less than 1%)
- Dyspepsia/Bloating/Abdominal Discomfort: 6 cases (less than 1%)
- Agitation/Nervousness: 3 cases (less than 1%)
- Macular Rash: 2 cases (less than 1%)
- Maculopapular Rash: 2 cases (less than 1%)

DISCUSSION

In the armamentarium of medications for pain, we believe that the side effect profile for many of these medications have been a significant and limiting aspect of many of these treatments. Our supposition for this study is that cannabidiol (CBD) potentially had a more advantageous side effect profile than some of the more traditional medications that are used for pain syndromes including tricyclic antidepressants, anti-epileptics, selective serotonin and norepinephrine reuptake antagonists, NSAIDS, skeletal muscle relaxants and opioids. We further feel that given the low side effect profile and emerging data clinically from our group and from published research³ on CBD in pain syndromes that healthcare providers may want to consider CBD as a first line treatment for pain syndromes.

LIMITATIONS OF STUDY

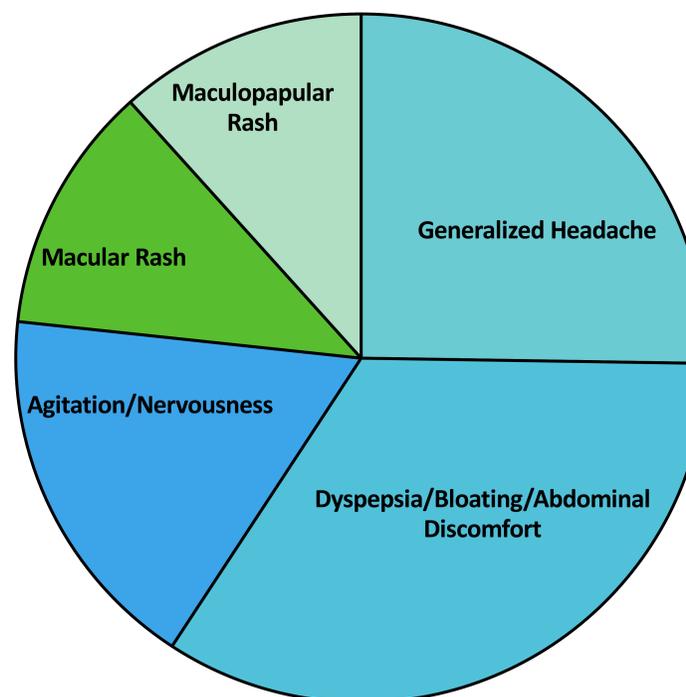
Limitations for this study included the patient primarily self reporting, rather than direct health care provider questioning on every clinic visit. For those included on the opioid reduction data, side effects felt to be from the opioids by the healthcare practitioner were not included in the side effect profile for CBD. Lastly, the lack of a control group may affect the results.

This study identifies CBD as a treatment with a low side effect profile from the patient perspective, however further studies are needed with in-depth serological analysis to look at any end organ system issues.

CONCLUSION

The data support the theory that CBD taken routinely carries a low side effect profile, with less than 1% self-reported side effects of a transient nature. This appears to warrant further study into the apparent broad safety profile of CBD. While we have no reason to think there are any prominent end organ system issues regarding cannabidiol, we are currently underway with this further evaluation.

Side Effects of CBD



References:

¹ Ther Clin Risk Manag. 2008 Feb; 4(1): 245–259

² JAMA. 2017 Nov 7; 318(17): 1708–1709

³ P. Fine, Rambam Maimonides Med J. 2013 Oct; 4(4): e0022