Medical Marijuana "Quality of Life Study" Wrap Up

James Warren McNally MD and Christian LeBouthillier CCPA

Our basic **working hypothesis** was that medical marijuana is **safe and efficacious** and should be prescribed within a family practice setting, the same as any other treatment modality would be prescribed and that prescriptions for medical marijuana **need not be referred** to specialized marijuana prescribing clinics.

Controversial Questions to be Answered:

Existing guidelines for prescribing Medical Marijuana are addiction-research based and rely on confirmatory "second looks" at historical data. Is this statistical misdirection through the use of meta-analysis and negatively based conjecture (a "Reefer Madness" bias), or an accurate warning?

Is the the recent empirical, observational data (e.g. success of "Charlotte's Web" in treating childhood epilepsy), a realistic reflection of the future potential benefits of prescribing Medical Marijuana, or are these isolated cases that won't be replicated?

Are the claims that Medical Marijuana is a viable treatment option, being resisted like the discovery of H. pylori as the underlying cause of gastritis and gastric cancer was initially rejected by a medical profession, heavily influenced by a pharmaceutical industry bias, or is this resistance justified, because these treatment claims for Medical Marijuana are simply pro-marijuana hype?

Integrating the Study into Our Family Practice:

We felt that the best way to answer these questions about Medical Marijuana was to conduct a **dynamic, prospective, longitudinal, observational study** to monitor the effectiveness of Medical Marijuana when prescribed in a family practice setting as part of the management of patients with chronic illness.

Counting rostered and unrostered patients, we have more than 3000 patients and interact with (through clinic visits, email, etc.) approximately 200 of them each week. Medical marijuana was considered and **prescribed as any other medication** and not as the primary focus of patient management.

By embedding and seamlessly integrating our study within the daily activities of a busy family practice, we hoped to remove some of the investigative bias that is more likely to occur when you isolate and focus more directly on a subset of patients and micromanage their cases.

If it turned out that our study results supported our basic working hypothesis, then a **secondary goal** was to establish simple **practical guidelines** for physicians to consider when prescribing medical marijuana for their patients.

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Our Approach to Patients:

During the year under study, June, 2015 to June, 2016, Medical Marijuana was discussed in depth with approximately 200 patients suffering from chronic pain, fibromyalgia and/or chronic anxiety, who were deemed **suitable candidate patients** for Medical Marijuana prescriptions.

Suitable patients for Medical Marijuana:

-**over 25** years of age.

-suffering with a **chronic condition** (chronic pain, fibromyalgia, anxiety).

-**not responding** well to conventional treatments.

After a patient was deemed a suitable candidate for Medical Marijuana, we discussed in more detail the possibility of prescribing Medical Marijuana as a treatment option.

To help patients navigate through the confusing number of marijuana strains and claims, we chose to simplify the description of medical marijuana products to:

-**High THC : Minimal CBD** (e.g. street marijuana, such as the classic "Acapulco Gold".)

-**High CBD : Minimal THC** (e.g. strains used to treat childhood epilepsy, such as "Charlotte's Web".)

- **Roughly 50:50 blends of THC and CBD** (a gray zone where results vary on an individual basis.)

We also gave patients a simplified explanation of marijuana plant types:

-Indica (ending in "ca" for more calming)

-**Sativa** (beginning with an "s" for more stimulating.)

-**Hybrids** (don't know, but we emphasized that the relative THC:CBD percentages are far more important to consider when selecting a strain.)

We encouraged **vaporizer** usage with leaf marijuana:

-to **avoid combustion** smoke, which is unhealthy.

-to **avoid "pot" odor** of marijuana smoke.

-to be more efficient, which **saves money**.

We encouraged patients to **titrate to the minimum effective dosage** that worked for them. The details of this discussion varied greatly, depending on whether or not the patient had experience with marijuana.

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Breakdown:

-Approximately **25%** of suitable patients (50 of 200) **declined prescriptions**, either because they considered Medical Marijuana to be **too expensive** or because of the **negative stigma** associated with marijuana usage.

Note: These patients were receptive to the idea of edible oils or capsules.

-Approximately **25%** of suitable patients (50 of 200) were **already using** street marijuana and/or non-legal sources of medical marijuana, such as storefront dispensaries, on a **regular basis**, with very positive results. Prescribing Medical Marijuana for these patients, was straight forward and simply facilitated their ability to access a more reliable and more trustworthy supply of marijuana for their medication needs.

Note: These patients in general felt that the medical community was behind the times and were suspicious of the specialized marijuana prescribing clinics.

-Approximately **25%** of suitable patients (50 of 200) **had tried** Medical Marijuana once or twice (sourced from family or friends) and found it helpful and wanted to discuss it's safety and use.

Note: A surprising 50% of suitable patients had already tried and knew that marijuana worked for them.

-Approximately **25%** of suitable patients (50 of 200) were **marijuana naive**, having never tried or used marijuana and required more detailed discussion of the pros and cons of Medical Marijuana, before they agreed to try it.

Note: These patients had a strong preference for the edible oils.

Edible oils became available toward the end of the study period and the idea was very attractive to the majority of patients, even the 25% of patients who initially declined any interest in Medical Marijuana.

All but the 25% of patients who were comfortable using street marijuana, preferred the idea of an edible oil or capsule form of Medical Marijuana.

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The Study:

For the study itself, we reviewed various assessment tools that were available and found them to be either too detailed and/or too confusing to provide us with a clear and honest answer to the core question of whether or not the use of Medical Marijuana had improved the **quality of life** for each specific patient.

In the end we decided to send a friendly email to patients who had been prescribed Medical Marijuana to invite them to participate in a simple, non-judgmental, online survey or to give us feedback at their next office visit.

-The content of the **email** that we sent and the **online survey** questions are attached.

We sent the email to 113 patients. We excluded those patients who didn't have email on file, declined to be involved, or who were related to or worked for any organization or company involved in the sale of Medical Marijuana.

We received 53 responses.

-Various **data files** and a **slide presentation** that was prepared are attached.

Conclusions:

-Medical Marijuana is a safe and effective treatment for chronic pain, fibromyalgia and chronic anxiety including any complex chronic condition that includes a component of pain and/or anxiety.

-The high CBD, low THC strains (e.g. Charlotte's Web) were the most surprising in that they worked well for some of the most difficult to treat patients, such as those with fibromyalgia, chronic pain (sciatica, musculoskeletal, migraine, trigeminal neuralgia, TMJ) and chronic anxiety.

-The vast majority of patients wanted to avoid anything resembling "getting stoned", because they wanted to be fully awake and functional during the day.

-Patients who were already using street marijuana were happy with the high THC strains, although those street marijuana users who liked THC for relaxing in the evening, preferred a high CBD, low THC strain for daytime use.

-Some of the unemployable and our one terminal cancer patient who died as expected during the year, preferred high THC strains anytime of day or night.

-The majority of patients preferred the idea of a high CBD, low THC edible oil or capsule form of Medical Marijuana. Note: Many are still waiting for product to be available.

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-With the risk of chronic use psychosis and with claims of an addiction rate running as high as 10% , most physicians are reluctant to prescribe or even endorse the use of Medical Marijuana. These risks are entirely based on strains high in THC and low in CBD (typical street marijuana). Rather than waiting for proof that these risks are exaggerated, cautious physicians can simply avoid the controversy and restrict their prescriptions to high CBD, low THC strains of Medical Marijuana (e.g. Charlotte's Web).

Note: It's currently hard to restrict what strains the patient can buy, but this should change especially as edible oils and capsules become available and more growers add the option to restrict patient strain selection.

-We found that the high CBD strains seem to be working the best, even for anxiety situations where the THC strains would seem to be preferred.

-The added advantage of focusing on the high CBD (e.g. Charlotte's Web) strains is that the low THC is going to make it easier to convince the cautious majority of physicians to prescribe it and will be generally easier to convince the skeptical patients to try it.

Practical Guidelines for the cautious and the skeptical

-Prescribe High CBD low THC strains of Medical Marijuana (e.g. Charlotte's Web) for fibromyalgia, chronic pain and chronic anxiety. This avoids the issues of potential psychosis and addiction, which are THC based.

-Prescribe Medical Marijuana as an edible oil. Have the patient start with 0.25ml to 0.5ml bid with breakfast and supper and slowly titrate upward to achieve the desired therapeutic effect with the lowest dose. (e.g. similar to titrating gabapentin).

-Only prescribe high THC strains, where the patient is already comfortable using them and the goal of the prescription is simply to legitimize their source and ensure the safely of their supply.

-Start by prescribing for patients who are already using marijuana.

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Final Comments:

The recent trend towards guideline driven medicine has advantages in creating a standardization of approaches to medical practice, but at the risk of reducing medical practice to a set of algorithms that can be administered by a robot, without thought or customization for individual patients.

The risk of over enthusiastically embracing guidelines is that guidelines tend to be interpreted as absolute rules or dogma, which creates a climate where carefully crafted statistical analyses of data can be used to promote the increased use of pharmaceuticals, which may or may not be ideal. The recent inclusion of the Sprint trial results into the CHEP hypertensive guidelines is a perfect example of how a flawed trial can march down the road towards becoming dogma.

The Sprint trial is flawed, which is suspect when you realize that the patients were not randomly selected for the 140mmHg target group vs the 120mmHg target group. Sure, the 140mmHg target group had more cardiovascular incidents, prompting the termination of the trial and a warning that 120mmHg should be the new systolic blood pressure target. The natural call for more medication to lower blood pressures, garnered immediate support from the pharmaceutical industry.

The flaw is obvious when you see that the average number of drugs to target for the 120mmHg group was 0.9, which should immediately tell the observer that this group was already close enough to target that some of the patients didn't even need medication to reach target. The family doctors choosing patients for the study naturally put their toughest patients in the easier to reach 140mmHg target group.

There is a reason that modern medicine is called the “practice” of medicine and not the “infallible” of medicine. We're supposed to be practicing our skills, learning as we go, while the patient is being patient.

The practice of medicine is meant to be a dynamic interaction between doctor and patient with an ideal goal of improving the patient's quality of life, while minimizing harm from treatments. This is how progress is made in treatments.

Something new and different makes sense, it's relatively safe, so we try it. Examples include how the observation that milk maids who had cowpox were immune to smallpox, led to vaccinations; how a contaminated culture plate led to the development of penicillin; how leaving cultures to grow beyond the standard two days, led to recognizing H. pylori as a gastric pathogen and perhaps now; how paying attention to the feedback we get from patients, may well lead us to incorporating high CBD strains of marijuana into our daily practice of medicine.