Ethical issues in medical cannabis use

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ABSTRACT

The increasing use of medical cannabis (MC) in the past decade raises several ethical considerations for the clinician. Regulatory issues stem from a gap between MC registration and certification in each country. Professional issues derive from the lack of sufficient knowledge of MC characteristics and the intersection between the physician, the patient and commercial interests. Finally, there are medical and psychological implications which are related to the use of MC regimens. We will discuss these issues in the light of the current era, in which policy has rapidly shifted toward legalization of cannabis, which influences the decisions of both clinicians and patients.

1. Introduction

Chronic pain conditions affect an increasing portion of the population worldwide [1,2]. Due to a lack of efficacy and frequent adverse effects of the standard therapies, the use of medical cannabis (MC) has emerged in the past decade in a bottom-up fashion. According to a 2005 survey, half of American adults have suffered from pain in the previous couple of weeks, 20% have rated their pain as "severe" and 6% (12 millions) have treated their pain with cannabis [3]. Similar rate of MC use was also reported in a Canadian survey [4].

There are many other disorders where great potential for the relief of symptoms by the use of cannabis exist but powerful clinical trial date is missing. In the past, large clinical trials which can be very expensive and time consuming have been organized and supported by pharmaceutical companies which have exclusive patent rights to the product. In contradistinction, medical cannabis is not under any patent protection and there is less incentive for pharmaceutical companies to perform the much needed clinical trials. This puts the individual physician in an ethical quandary as for many conditions the relevant clinical data is missing and in many cases the physicians is legally required to use the more expensive and perhaps less efficacious medication. In order to overcome this problem large clinical trials on a variety of medical conditions are necessary not only to look for efficaciousness but also potential side effects and long term outcomes. The growing reluctance among many physicians to prescribe opioids for non-oncological pain disorders also highlights the importance of obtaining the necessary clinical trial date. However, the frequent use of MC also raises ethical issues for consideration by the medical professionals.

In this review we will discuss these issues in the light of the increasing medical use of MC. First, we will discuss regulatory considerations of MC use. Second, we will turn to professional perspectives. Third, we will consider the medical and psychological considerations of MC use.

2. Regulatory and ethical considerations

The synthetic oral tetrahydrocannabinol (THC) named “Marinol”, has been approved by the Food and Drug Administration (FDA) in 1985 [5]. In the past decade, the oromucosal spray named Sativex which contains THC and cannabidiol in a nearly 1:1 ratio, has been approved for use in the United Kingdom, Canada and several other countries [6]. As opposed to the two approved cannabis agents mentioned above, most popular MC are dried cannabis plant derivates, consist with THC and CBD in variable levels. Different strains of MC may influence differently due to their THC and CBD content and ratio of these two ingredients [7].

There is insufficient high quality data regarding the efficacy, dose-dependent curve, drugs interactions, expected adverse effects and safety of the commercial available MC products. For instance, smoked MC, a frequent method to utilize CM, has a very low bio-availability and was linked to a wide range of respiratory adverse effects, e.g. cough, phlegm and bronchitis [8]. The poor RCT's data also impairs the ability to define clear clinical indications to use MC. Consequently, physicians can prescribe MC for any indication they choose (e.g. vague indication...
as “chronic pain”) rather than clear evidence based conditions [9]. Due
to these gaps there is a long way to go until more MC regimens will
receive FDA approval. Since there is a lack of data especially from RCT’s
regarding the efficacy and safety of each regimen according to its
TCH:CBD ratio, these gaps may impair the decisions made by physi-
cians regarding tailoring the optimal therapy for each patient.
A different regulatory issue stems from the US federal governmental
laws. Marijuana is defined as illegal drug by the U.S FDA. It is classified
as Schedule I under the Controlled Substances Act, meaning that ‘it has
no currently accepted medical use and a high potential for abuse’ [10].
Due to its status, physicians cannot prescribed MC and rather can only
give certification to its use.

3. Professional perspectives

The use of MC poses several ethical considerations to the physicians
in their practice. As mentioned above, physicians are expected to pre-
scribe unstandardized agents with no FDA approval, but with poten-
tially unexpected effect and adverse reactions. Physicians are also re-
quipped to discuss with their patients’ potential risks and benefits before
prescribing any treatment or medication. Since MC dosing and potency
is not regulated, there is an unavoidable knowledge gap. Not surpris-
ingly, most of the family physicians in Colorado (a state with high rate
of marijuana use) stress that marijuana’s health risks overweight their
benefits, and nearly all agreed that routine utilization of MC needs
further education [11]. There is also a lack of data on the long term
effects of cannabis use [12] which impacts on physician and patient
decision making. Moreover, the relationship of some psychiatric con-
ditions with cannabis utilization remained unclear, as previous studies
reported an increased risk for developing depression among chronic
consumers users [13].

In several countries MC certification is given only to specific phy-
sicians or nurses, who are authorized by the local health ministries
[14]. This situation may turn into a reality, where certain caregivers
will be involved mostly in the distribution of MC certifications rather
than providing routine health care.
The most popular administrating method of MC is by smoking [15]
and this topic has several important ethical implications. Besides the
effect of smoked MC on the respiratory tracts of the users, it may also be
associated with second hand smoke effects on the environment. For
instance, second hand cannabis smoke was reported to produce detec-
table levels of THC in blood and urine, and minor impairment on
psychomotor abilities and working memory [16]. Second hand can-
nabis exposure was also found to be associated with lower cognitive
functioning among exposed children [17] and increase emergency visits
among children exposed to second hand cannabis smoke after legali-
ization [18]. These findings imply that smoked MC contradicts the harm
principle, in which an individual is free to abuse illicit agent unless it
does not harm others. On the other hand, smoked MC is administrated
easily, with a shorter half-life but higher bio-viability compared to oral
MC regimens [7]. This issue emphasis the principle of respect of au-
tonomy, since some would prefer to use smoked or vaporized MC,
which will be most suitable for their needs. These two contradicting
ethical considerations need to be balanced, and should be kept in mind
during routine patient-physician interaction on this topic.

An additional concern relates to the intersection of medicine and
commercial interests. Since there is no clear guidelines of when
to prescribe MC, the vague indications and relatively high availability of
MC may lead to over-use, misuse and eventually to illegal trading with
third party similar to the broad use of opioids [19,20]. These undesir-
able trends may be pushed by commercial interests, which might jeo-
pardize both clinicians’ integrity and patients’ well-being. For instance,
commercialization of cannabis in the U.S has been associated with
higher risk perception of cannabis, and was associated inversely with
increase use of cannabis among youth [21,22]. Forty percent of ado-
lescents reported obtaining marijuana from someone with a MC license
[23]. Consequently, this finding implies that patients with approved MC
material may pass or trade the drug with a third un-authorized party.
MC exposure was found to be related to cannabis availability of any
type and increased frequency of use, especially among the vulnerable
group of adolescents. In this case, there is an actual concern that MC
dispensaries may be the stalking horse for increased commercial dis-
tribution of cannabis to the entire public, rather than to the those who
have relevant health concerns. On the other hand, when dealing with
those who do receive medical certification to use MC, no insurance
companies provide coverage to MC, which further exacerbates the
burden on patients.

4. Medical and psychological implications

The use of MC has several risks due to short-term and long-term
utilization [24]. Almost 10% of those who use cannabis will become
addicted to it [25]. In addition, the development of cannabis with-
drawal syndrome makes more difficult the cessation of cannabis use
[26]. Apparently, adolescents are the most vulnerable group, as they
show 2–4 folds likely to develop cannabis dependence compared with
adults [27]. Moreover, chronic cannabis utilization was found to de-
terio-rate the brain functioning connectivity especially among young
adults [28]. This explains why frequent use of cannabis during ado-
lescence period was associated with declines in IQ measurements [29].
Furthermore, several epidemiological studies have reported the role of
cannabis utilization as a gateway drug to the consumption of other
substances later in life, due to reduced dopamine activity in the brain’s
reward region [30,31]. The use of MC or legal recreational cannabis can
also be seen in the context of self-medication hypothesis of addictive
disorders, where patients utilize drugs to relieve painful (physical or
emotional) states. These states are important psychological predictors
for utilization and in developing dependency on addictive drugs instead
of treating with the initial trigger that have created these conditions
[32]. Chronic and even short term use of cannabis were also linked to
depression, anxiety, acute psychosis disorders and schizophrenia (the
latter was reported among users with preexisting genetic vulnerability)
[33,34]. There is evidence that even relatively short term exposure to
cannabis is associated with poor educational performances and in-
creased risk to dropping out of school [35].

These short and long term consequences of MC use can put the
physician who prescribed them in a constant conflict. Although every
drug has adverse reactions, as stressed above, quality RCT’s on MC re-
gimens and more specifically on substances with alternating THC:CBD
ratio are scarce. Consequently, when discussing with patients the ex-
pected effect and adverse effect of each regimen there is a substantial
information gap that impair receiving proper informed consent from
patients prior to any initiation of MC therapy.

5. Conclusion

The increasing use of MC in the past decade consists of regulatory,
professional and medical ethical considerations. Although most of these
concerns are common to any medical regimen with potential risk, some
are unique to MC utilization. Physicians who certify their patients to
use MC, encounter several conflicting ethical issues as discussed above.
The use of MC is associated with lack of sufficient knowledge regarding
the exact content and purity of MC derives, expected dose response
relationship, adverse events and interaction with other drugs. These
gaps impair the patients ability to reach a fully informed decision since
many issues of MC pharmacokinetics and pharmacodynamics are still
unclear. The lack of sufficient knowledge may lead to undesirable harm
to the patients, which contradict the physician’s principle of non-mal-
eficence. On the other hand, since many patients prefer administrating
MC via smoking methods, their right to autonomy (choosing the best
route of administrating for them) interfere with the no harm principle,
which stems from the right to self-abuse substances. The involvement of
commercial cannabis dispensaries can expose patients to outside influences, thereby impairing their autonomy to make decisions unrelated to other influences. The use of legalized substances such as alcohol, tobacco and soon cannabis, accounts for a greater burden than other illegal drugs, due to their widespread use rather than their actual harms [36]. It is important to bear in mind that while the policy is rapidly shifting toward legalization of cannabis and expending the use of MC, there are still numerous ethical considerations that need to be resolved along the way.

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