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Kannabinoidy jako nowa klasa koanalgetyków w Polsce.

Rozprawa na stopień doktora nauk medycznych i nauk o zdrowiu
w dyscyplinie nauki medyczne

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Summary

Medical cannabis, i.e., *cannabis* typically containing tetrahydrocannabinol (THC) for medicinal purposes, has recently become the subject of extensive public debate. Controversy over its health effects, the potential for addiction, and other recreational use implications have clashed with proponents' arguments attributing medicinal and health-promoting properties to the *cannabis* plant, often without a sound scientific basis. As a result of these disputes, *medical cannabis* has become legal in more than 30 U.S. states and recreational marijuana in more than ten, but the number is still growing.

Poland joined the states in allowing the use of *cannabis* for medical purposes in November 2017 due to an amendment to the Anti-Drug Addiction Act. According to it, *cannabis* constitutes a pharmaceutical raw material, which becomes a drug as a result of the very act of dispensing it in a pharmacy. As it stands, Polish legal regulations regarding *cannabis* in medicine are quite liberal. Any physician may issue a prescription, including a physician without a specialist title, for any therapeutic indication and an unlimited quantity. Indeed, currently, a patient may possess a supply of *cannabis* sufficient for 90 days of treatment, but there is no limit on the amount of raw material. There is no list of permitted indications or contraindications for *medical cannabis* use in Poland, while in most European countries, they are strictly defined. There is also a lack of guidelines created by the Ministry of Health or Scientific Societies to help physicians use *cannabis* and cannabinoid-containing drugs in clinical practice.

Pain is the leading complaint for which *medical cannabis* is prescribed worldwide, and it is also a significant clinical problem. Approximately 20% of the adult population lives with chronic moderate to severe pain. Although this is just a coincidence, in 2017 - precisely the same year in which the legal conditions were created to allow the use of *medical cannabis* in Poland, an amendment to the Act on Patients' Rights and Patients' Ombudsman was also passed. A provision on the patient's right to pain treatment was then added, and healthcare providers were required to monitor its intensity and treat it. That indicates a growing awareness of the need to alleviate suffering and evaluate pain as a symptom and a health problem in its own right.

The Polish patient coping with pain encounters many difficulties accessing effective analgesic therapy. According to the Supreme Chamber of Control's report "*Availability of Analgesic Therapy*", compiled in 2016, 5 out of 16 provinces had more than 200,000 people per pain management clinic, and 8 out of 16 had more than 300,000 people. However, no pain management clinic was available in 266 out of 380 counties (including cities with county rights). At the same time, the number of patients on a waiting list for pain treatment increased dynamically. In 2015, by March 30, in 7 controlled outpatient clinics, 447 patients were awaiting consultation, whereas in 2016, by March 31 - 738. The waiting time for consultation reached 123 days. A significant problem is the issue of financing pain counseling by the National Health Fund within the inspected facilities. In 2015, 1.3 million PLN was allocated for this purpose, and in 2016 it dropped to 1 million.

Another problem with pain treatment in Poland is the underutilization of analgesics, which remains low compared to Western European countries. These differences in Europe are attributable to governmental policy factors and lack of awareness and education of health care professionals. In addition to educational deficits, cultural differences also contribute to Poland's situation. Like opioids, cannabinoids are also controlled drugs with a reputation of being '*dangerous drugs*'. THC is still legally classified as an I-P psychotropic, with a high potential for abuse and no therapeutic value.

In recent years, more attention has been paid to examining the opinions and attitudes of medical professionals toward the therapeutic use of cannabinoids. Legislative changes regarding the medical uses of *cannabis* are impacting their clinical practice, and due to the role of physicians in the health care system, they are key players in these changes. At the same time, the public debate on this topic is primarily driven by emotions rather than reason. Therefore, the voice of the medical community, which often dampens the conflicting feelings of supporters and opponents of legalization, is less audible. Therefore, whenever changes are made that affect the delivery of health services, it is essential to learn the perspectives of each social group subject to the changes - not only patients but also physicians. The following dissertation includes publications of research results, which consider various aspects related to the use of *cannabis* and medicines containing cannabinoids in medicine in the opinion of Polish physicians.

Aim of the study

The overall aim of the study was to assess the attitudes, opinions, and educational needs of Polish physicians in the context of a new class of co-analgesics - cannabinoids. Specific aims are presented below:

- 1) To explore physicians' attitudes and opinions towards systemic solutions in the scope of legalization of *medical cannabis*.
- 2) To understand the attitudes and opinions of physicians regarding the clinical aspects of the use of *cannabis* in medicine.
- 3) To evaluate the needs of physicians in terms of education and preferences for systemic solutions involving medical uses of cannabinoids.

Material and methods

The study describes the attitudes and opinions of physicians from Poland regarding the clinical utility of cannabinoids, their safety profile, as well as educational needs, and suggestions for systemic solutions. Data from studies performed in other European countries are also discussed and compared. The series of publications presents a multifaceted view on the use of controlled substances in medicine, showing it through the prism of a new class of co-analgesics – cannabinoids.

Participants in the study were physicians recruited during a course in palliative medicine organized by the St. Christopher's Oncological Hospice Foundation in Warsaw

(FHO) and through District Medical Chambers, professional portals/newsletters for physicians, and social media groups dedicated exclusively to medical professionals. A total of 173 physicians were recruited for the study. Due to the COVID-19 pandemic outbreak, the survey was conducted online. Participants remained fully anonymous - no contact details or IP addresses were collected. Participation in the survey was voluntary.

. The survey consisted of 5 topic sections and included 57 questions:

- 1) Demographics
- 2) Opinions regarding the desired availability status of cannabinoid medications
- 3) Clinical practice
- 4) Willingness and factors motivating for further professional training
- 5) Personal experiences with recreational use of cannabinoids and other psychoactive substances

In order to answer the research questions posed, statistical analyses were performed using the IBM SPSS Statistics version 26. That software was used to analyze basic descriptive statistics; afterward, Mann-Whitney tests, multinomial logistic regression, chi-square tests of independence, and Fisher's exact test were performed. The classical threshold of $\alpha = 0.05$ was taken as the level of statistical significance.

Results

From June to October 2020, 173 physicians from 15 provinces were recruited for the study. The largest age group (43.9%; $n = 76$) were 30-39 year-olds.

Support for the legalization of *medical cannabis* was expressed by 147 out of 173 physicians participating in the study (85.0%). An overwhelming number of physicians disagreed (78%; $n=135$) with the statement, "*I am not interested in medical uses of cannabis*". Similarly, a high proportion of physicians felt that cannabinoid drugs (71.7%; $n=124$) and dried cannabis flowers (52%; $n=90$) should be reimbursed. The majority of participants disapproved of solutions that potentially restrict access to cannabinoid treatment, such as the need to apply to an authority/committee to initiate treatment (82.1%; $n=142$ were against such a solution) and the requirement of a psychiatric consultation for all patients prior to starting cannabinoid therapy (62.4%; $n=108$ were against). More than half of the survey participants did not support the establishment of a registry for patients using *cannabis* for medical purposes or a similar registry for physicians authorized to prescribe *cannabis* (for both questions, 52.0%; $n=90$).

The most frequently selected indication for *cannabis* use by respondents was pain: chronic cancer-related ($n = 128$), chronic noncancer ($n = 77$), and neuropathic ($n = 60$). Other frequently selected indications were relief of side effects of anticancer treatment ($n = 56$) and cachexia ($n = 57$). The overall safety profile of THC was evaluated as similar to the most

commonly used drugs, including opioids, while non-steroidal anti-inflammatory drugs (NSAIDs) and benzodiazepines were perceived to be safer.

Half of the study participants said they had patients in their practice who could potentially benefit from cannabinoid drug therapy, and 53.8% had admitted at least one patient actively requesting such treatment in the past six months. However, only 15 (8%) of the surveyed physicians had ever prescribed a prescription for *cannabis* or other cannabinoid medications.

Most survey participants had never attended training or lectures on *medical cannabis* (60.1%; n=104), whereas 71.1% (n=123) reported having insufficient knowledge to advise patients on cannabinoid use. However, the majority said they would like to be knowledgeable enough to be able to answer patients' questions about *cannabis* (92.4%; n=160). The vast majority of physicians (93.1%; n=161) stated the need for clear guidelines on cannabinoid use in clinical practice.

Conclusions

1. The vast majority of physicians support the introduction of *medical cannabis* on the market and reimbursement of drugs containing cannabinoids. There was less support for the reimbursement of herbal *cannabis*. However, solutions potentially limiting access to such treatment for patients, such as the need to apply for initiation of therapy and the requirement of additional specialist consultations, met with less approval among the surveyed physicians.
2. The most common indications for the therapeutic use of *cannabis* were pain, including cancer-related and neuropathic pain. However, only a few physicians had used cannabinoids on their patients.
3. Physicians perceive their level of knowledge as insufficient to answer patients' questions. Nevertheless, most of them would like to be qualified and knowledgeable to advise on cannabinoid use. The vast majority indicate the need for creating recommendations on the use of *cannabis* in clinical practice.
4. The majority of physicians have not attended any training or lectures on cannabinoid therapy, which indicates a need to expand educational efforts regarding the medical uses of cannabinoids.