A Comprehensive Patient and Public Involvement Program Evaluating Perception of Cannabis-Derived Medicinal Products in the Treatment of Acute Postoperative Pain, Nausea, and Vomiting Using a Qualitative Thematic Framework

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Abstract

Introduction: Cannabis-derived medicinal products (CDMPs) have antiemetic properties and in combination with opioids have synergistic analgesic effects in part signaling through the delta and kappa opioid receptors. The objective of this patient and public involvement program was to determine perception of perioperative CDMPs in our local population to inform design of a clinical trial.

Methods: A qualitative evaluation was conducted utilizing a focus group, semistructured interviews and a community event. Analysis was conducted through the framework methodology. Verbatim transcriptions were coded categorically into analytical frameworks for thematic analysis. Emergent themes and associated degree of consensus/dissent were determined. The participant cohort was composed of a group of patients and relatives representative of the target population (M:F = 1:1, age range 33–85).

Results: Most common coding categories in thematic analysis framework included side-effect profile, trial schedule of events, and safety. Consensus was that potential benefits of CDMPs were attractive compared with the known risk profile of opioid use. Decrease in opioid dependence was agreed to be an appropriate clinical end-point for a randomized controlled clinical trial and there was concurrence of positive opinion of a therapeutic schedule of 5 days. Negative CDMP perceptions included addiction, dysphoria, and adverse effects in psychiatric subpopulations. Sublingual or oral administration was the most acceptable route of administration, with some expressing that inhalation delegitimizes therapeutic properties.

Conclusions: The perception of postoperative CDMP therapy was overwhelmingly positive in this West London population. The data from this thematic analysis will inform protocol development of clinical trials to determine analgesic and antiemetic efficacy of CDMPs.

Keywords: antiemetic; cannabinoid analgesia; medical cannabis; pain

Introduction

Postoperative nausea and vomiting (PONV) and pain control are important patient-related outcomes.¹ PONV, while important for patient comfort, can also result in adverse effects, including aspiration of vomitus, electrolyte imbalances and dehydration, wound dehiscence and reac-

tive hemorrhage. Precise anesthetic assessment in the preoperative environment is necessary to reduce the risk of PONV, utilizing risk assessment methods such as the Koivuranta score and the Apfel score, to guide antiemetic management.² Prescription of antiemetics reduces the incidence and severity of PONV, however, typically they are

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used in a combination therapeutic regimen to increase efficacy. This increases the rate of adverse drug events in medications that already have well-established side effects.^{2,3} Acute postoperative pain is associated with an increased length of hospital stay, pulmonary and cardiac complications, and development of chronic pain.⁴ Despite the advent of novel anesthetic techniques, systemic pharmacological techniques, in particular opioids, are heavily utilized for acute postoperative pain.⁵ Opioids, while also increasing the risk of delirium, PONV and bowel dysfunction following surgery, are addictive. Analysis of the United States opioid epidemic identified that 5% of opioid-naïve patients take opioids long term following a prescription for acute postoperative pain.⁶

Multimodal opioid-sparing anesthetic techniques have shown beneficial effects in achieving adequate control of PONV and acute surgical pain, however, are underutilized in clinical practice.⁷ Cannabis-derived medicinal products (CDMPs) are potential opioid-sparing agents due to their known effects on pain, nausea, and vomiting. Over 113 chemical compounds have been extracted from the cannabis plant.⁸ (–)-*trans*- Δ^9 -tetrahydrocannabinol (THC), the most widely studied active component of the cannabis plant, demonstrates antinociceptive and anti-inflammatory properties through the endocannabinoid system.⁸ Cannabidiol (CBD) acts primarily outside endogenous cannabinoid receptors to reduce inflammation, pain, and nausea.⁸ Both THC and CBD have numerous neuroreceptor targets, including G-protein-coupled mu and delta opioid receptors.^{8,9}

Clinical evaluations support the use of CDMPs as a treatment for chronic pain, including for patients with cancer.^{10,11} A recent Cochrane review has also supported CDMPs in treating nausea and vomiting in cancer patients receiving chemotherapy.¹² There is a paucity of high-quality data supporting its use in acute postoperative nausea, vomiting, and pain. Only five studies have sought to evaluate this previously, which are subject to methodological limitations.^{13–17} The effect of CDMPs is dependent upon concentrations of THC, CBD, and other cannabinoids. For example, compounds with high concentrations of CB1 and CB2 agonists regulate emesis effectively, whereas antagonists potentiate nausea and vomiting.¹⁸ Meanwhile studies seeking to evaluate the effect of CDMPs on pain have been unable to generate a clear conclusion of efficacy.¹⁹ However, preliminary studies suggest that CDMPs may pro-

vide opioid-sparing effects, a clinically important outcome in perioperative medicine.^{19,20} Clinical research in CDMPs is therefore likely to face additional challenges beyond normal pharmaceuticals. As such, clinical trial methodology will be of the upmost importance and this will require patient and public input.

Questionnaire evaluation of perioperative patients identified that they believe that CDMPs may improve postoperative pain, indicating patient-level desire for the adaptation of CDMPs for postoperative use.²¹ Following change in legislation to legalize CDMPs in the United Kingdom on November 1, 2018, there is urgency for more robust data to guide clinicians. The aim of this patient and public involvement (PPI) initiative was to determine perception of perioperative CDMPs in our local community through in-depth semistructured interviews, focus groups, and a community PPI event. The findings will inform the design and clinical end-points of a double-blinded, randomized controlled clinical trial (RCT).

Materials and Methods

A qualitative PPI program was initiated at Hammer-smith Hospital, Imperial College London. The first stage described in this article involves a large focus group ($n=14$), and separate semistructured interviews ($n=4$). The second stage was a community PPI event. The full program will accompany a clinical trial. All interviews were conducted using local ethical principles and information governance practices. The reporting of the PPI program is conducted according to GRIPP2 reporting standards.²²

Recruitment

Participants in the focus group and interviews were identified from the Imperial College Hepato-Pancreato-Biliary (HPB) surgery service. Inclusion criteria included preoperative and postoperative patients. Patients were excluded if they did not have adequate English comprehension skills to engage in oral discussion. Participants were required to provide written informed consent to engage in the sessions. They were reimbursed for time and travel in accordance with PPI engagement principles.

Participants in the community PPI event were recruited from the surrounding population of London through paper and internet-based advertisements. There were no restrictions placed on the number of participants taking part.

Focus group

The focus group was conducted in a quiet seminar room to prevent distraction. A member of the research team (M.M.) moderated the session using a semistructured approach (Table 1). Minutes were transcribed in real-time.

The first 10 min were allowed for introductions, implementation of ground rules, and a presentation of a proposed trial design. The proposed trial design detailed a placebo-controlled, randomized controlled trial of CDMPs alongside current analgesic gold standard for patients undergoing major HPB surgery. Proposed primary end-points included opioid-sparing effect of regular CDMPs through objective patient-controlled analgesia (PCA) evaluation, pain scores, and nausea and vomiting scale assessments.

Interviews

A member of the research team (S.E.) conducted semistructured interviews with four participants (Table 1) lasting 30–45 min each. These sessions began with a 5-min introduction and presentation of the proposed trial design.

Table 1. Semistructured Interview Guide

1. Introduction
<ul style="list-style-type: none"> • Gain consent • Participants and moderators introduce themselves • Presentation on outline of proposed study protocol
2. Understanding of CDMPs
<ul style="list-style-type: none"> • What do you understand about the laws around medicines that have been made from cannabis? • Have you heard about the use of any medicines made from cannabis? • What do you think these medications could be used to treat?
3. Views on safety and efficacy of CDMPs
<ul style="list-style-type: none"> • How safe do you think these medicines are? • How effective do you think they are? • What makes you think this?
4. Views on side effects and comparison to opioids
<ul style="list-style-type: none"> • Do you know anything about the side effects of these medicines? • What do you know about the side effects of opioids? • How do you think the side effects may compare between the two groups
5. Views on administration
<ul style="list-style-type: none"> • How you would you feel about administration methods? • Which method would you prefer? • Which would not be acceptable to you and why?
6. In-depth understanding of trial
<ul style="list-style-type: none"> • What are your initial opinions of this trial? • Do you think it is relevant to you/other patients? • Are the end-points /outcomes (remind them what they are) relevant • Would any other outcomes also be relevant? • How could these be measured? • What do you like and what do you not like about the trial and why? • Would you participate in this trial? • How do you think information would be best presented to patients?
7. Closing
<ul style="list-style-type: none"> • Is there anything else you would like to discuss • Thanking everyone for their time

CDMPs, cannabis-derived medicinal products.

Community PPI event

The community PPI event entitled “People’s Research Café” was conducted at a community center in London. This utilized a novel research methodology devised by a cross-center approach at our institution.²³ The event was run by mock “baristas,” a diverse mix of researchers and public partners, who would provide a lay summary of the proposed clinical trial. Attendees were invited to answer questions in a semistructured format (Table 1). The benefit of this approach is through an informal atmosphere it allows participants unfamiliar with traditional PPI methodologies to have more open conversation with the authors.²³

Analysis

Thematic analysis of the discussions was conducted using the Framework Methodology.²⁴ Voice recordings of the interviews were made with participant consent to allow for verbatim transcription. Each recording was transcribed and subsequently crossmatched with the audio to ensure accuracy. The transcriptions were interrogated for relevant discussion. Discussions from the focus group and community PPI event were unable to be recorded due to logistical constraints, however, quotations were recorded precisely at the time of discussion to ensure accuracy of discussants’ viewpoints. The discussions were independently coded according to theme through a consensus approach by two researchers. The analytical framework was created by assigning codes to different categories. The data were then summarized in a matrix for each category. Emergent themes and degree of consensus and dissent were determined through this process. All analyses were conducted using Microsoft Excel (Microsoft, Redmond, WA).

Results

Eighteen participants took part in the first stage of the PPI program (focus group $n = 14$; M:F = 1:1; age range 33–85). Three participants were preoperative. A broad range of participants attended the PPI café ($n = 23$). Due to the informal nature of the event, demographics were not collected. The final analytical framework consisted of 25 defined codes, clustered in three categories (Table 2).

CDMP perceptions

Thirteen separate codes were isolated regarding CDMP perceptions. On discussion it was noted that patients already had prior knowledge of the medicinal properties of

Table 2. Transcription Codes Categorized Through Themes

Code	Description	Focus group	Interview 1	Interview 2	Interview 3	Interview 4	PPI café
CDMP-product perceptions							
Licensed use	What conditions can CDMP be used in?	✓	✓	✓	✓		✓
Medicinal benefits	Symptom control and actions of CDMP which provide medical benefit	✓	✓	✓	✓	✓	✓
Side effects of CDMPs	Perceptions of CDMP side effects	✓	✓	✓	✓	✓	✓
Safety	Perceptions about the safety of CDMPs	✓	✓	✓	✓	✓	✓
Production	Beliefs about the production of legal and illegal cannabis	✓					
Availability	Access and costs of CDMPs						✓
Addiction of CDMPs	Beliefs about the risk of addiction to CDMPs and illicit cannabinoids	✓	✓	✓	✓		✓
CDMPs and mental health	Beliefs about the effects of CDMPs and cannabis on population mental health	✓					✓
Cannabis laws	Perceptions about the legal availability of CDMPs and cannabis	✓	✓	✓	✓	✓	✓
Cannabis and religion	Religious implications of cannabis use	✓					
CDMPs and the media	Media portrayal of CDMP use	✓	✓		✓		✓
Personal CDMP use	Personal experience with CDMP—benefits and harms	✓					
Personal cannabis use	Personal experiences with cannabis	✓		✓			
Medical administration of CDMPs	Best methods to improve acceptability of CDMPs when taking in a medical context.	✓	✓	✓	✓	✓	✓
Opioid perceptions							
Medicinal benefits of opioids	Symptom control and actions of opioids which provide medical benefit	✓	✓	✓	✓	✓	✓
Side effects of opioids	Perceptions about opioid side effects	✓	✓	✓	✓	✓	✓
Opioid addiction	Beliefs about the risk of addiction to opioids	✓	✓	✓	✓	✓	✓
Trial perceptions							
Consent	How best to conduct consent and relay information about the trial to lay persons	✓		✓			
Pain	Thoughts about how to best assess pain	✓	✓	✓	✓	✓	✓
Nausea and vomiting	Ideas about how to best measure nausea and vomiting	✓					
Postoperative side effects	Beliefs about how we could best capture side effects and what side effects are unacceptable in the postoperative period	✓	✓	✓	✓	✓	✓
Quality of life	Encompassing of general quality of life as an endpoint				✓		
Frequency of data collection	How often patients should be asked about primary endpoints	✓	✓		✓		
Night-time data capture	Thoughts about whether data capture should continue overnight	✓	✓				
Length of follow-up	How best to follow up patients	✓					
Participation	Factors that contribute to patient's attitudes toward taking part in the research.	✓	✓	✓	✓	✓	✓

PPI, patient and public involvement.

CDMPs. Of note, three participants had personal experience with administration of CDMPs, in particular CBD, for multiple sclerosis, anxiety and arthritis, and asthma, respectively. One patient had used cannabis recreationally. Most discussants were aware of acquaintances using the

medicinal properties of CDMPs in the United Kingdom and abroad. Participants expressed that they believed that CDMPs could have a role to play in acute postoperative pain management, but also in a range of conditions, including chronic pain, multiple sclerosis, and cancer.

Most knowledge stemmed from media coverage of CDMPs, and in particular their recent category status change in the United Kingdom:

"I am a member of the public, so all I know is what the media tells me, which is that it is becoming legal for medical purposes and otherwise it remains a class A banned drug." (Interview 1)

Participants were concerned about the safety of CDMPs considering their limited use currently in the United Kingdom. While our local population were not deterred by the legal status illicit substances derived from the cannabis plant, they did indicate that this might be a barrier to research and future declassification for medicinal purposes.

Safety concerns included the potential effects on mental health:

"I have seen people taking cannabis in Africa—not eating and using cannabis—leading to mental health problems." (Focus Group)

In addition, participants were concerned about potential addictive properties, dysphoria, or invoked anxiety. Some participants were concerned that CDMPs may encourage the use of recreational cannabis, which would be unregulated and may have unforeseen consequences.

"Would participants be prone to using recreational cannabis as they're now exposed to medical cannabis?" (People's Research Café)

There was discussion about the implications of CDMPs and religion. There were conflicting thoughts about how CDMPs would be perceived within the context of religion, including varying interpretations of how use of products derived from a cannabis plant would be interpreted by Islam.

On discussion of medical administration, preferred methods included use as a tablet or sublingual application. It was suggested that smoking or inhalation would delegitimize the medicinal properties of CDMPs:

"I just think that smoking has so many other associations that it would illegitimize [sic] the potential medicinal effects and I think you would have a hard time convincing patients, certainly of my generation from taking it." (Interview 3)

Some participants turned their thoughts to the long-term implications of CDMP licensing, with concerns over access to medication and financing.

"How much will it cost in the future? Will it be affordable for me?" (People's Research Café)

Opioid perceptions

Fifteen participants had previous experience with opioid use in the postoperative period. Symptomatic benefit was highlighted as a positive of opioid use:

"...my overall impression was that I was very fortunate that if there were blips in the pain control [whilst using opioid based patient-controlled analgesia] then I don't remember them." (Interview 3)

Patients noted a number of side effects, including dry mouth, dysphoria, constipation, myoclonus, and nausea. One patient on reflection noted severe pain subsequent to opioid-induced constipation:

"The next day I went to the toilet and it was bad, I needed to call 999." (Interview 2)

Another patient reflected on his experience with postoperative nausea, exaggerated while on opioid medication:

"I really couldn't stand nausea; to me it's worse than pain." (Interview 1)

Opioid-related addiction was mentioned as an important indication for reducing opioid prescribing in the focus group and all interviews.

Trial perceptions

All participants were supportive of the trial aims and believed randomization with placebo to be acceptable in coadministration with current analgesic gold standard. Only two people indicated that they would not take part in the study, secondary to their religious beliefs and previous mental health issues, respectively.

The consensus decision among participants was that measurement of PCA use postoperatively would be an effective way of measuring pain control and opioid requirements. Beyond this, measurement of pain through a subjective scoring system was also emphasized. For most participants this took the form of a pain scale. Issues were identified with this:

"When you measure pain people would ask me on a scale of 1–10 and I always find that very difficult to answer. One reason is when I was a teenager I was very badly burnt and you never forget that pain and it's off the scale... You could ask people like me what's the worst pain you've had and I can still remember it and then do a comparison against that. So in my case it wouldn't be very useful, but it might be of more use to the surgeon. Then it may be more accurate in a way." (Interview 1)

Nausea and vomiting were regarded as important outcomes. However, no obvious solution to measuring nausea and/or vomiting was determined:

“To me for nausea it is a binary thing you’re either nauseous or you’re not there’s not scale.” (Interview 1)

Study participants believed it was important to capture medication side effects. Length of follow-up was agreed to be dependent on the type of surgery any study on medication is seeking to capture. However, there was a high concurrence for a 5-day therapeutic schedule.

One participant also believed that a quality-of-life measure is an important study outcome:

“I think it’s very important to look at the person as a whole... what is the best result from them in their totality as a whole person.” (Interview 3)

Participants believed that as pain, nausea, and vomiting could occur at fleeting moments it is important to frequently assess these each day with a range of 2–6 times daily proposed. Most participants thought it would be inappropriate to wake patients up in the night for assessment, but believed early morning interview would be essential in determining night-time symptoms.

Discussion

This study aimed to investigate patient and public perception of CDMPs in the postoperative environment to treat acute surgical pain and PONV to help inform future trial design. The results of this study suggest that there is agreement between patients in positive opinion toward further investigation of CDMPs for this purpose.

These results are concordant with other investigations into public perceptions of CDMPs. A survey of the U.K. population demonstrated that 76% of respondents would be open to consuming CDMPs if obtained through a prescription.²⁵ Moreover, there is cross-party support for legalization of cannabis for medical use indicating that there is likely to be further relaxation of prescribing restrictions in the United Kingdom.²⁶ A questionnaire evaluation of perioperative patients indicated that 81.5% and 82% of patients would be willing to take CDMPs for acute postoperative pain and chronic pain, respectively.²¹

It is clear from our data that the reasons behind this are linked to both perceptions around CDMPs, but also opioids in the perioperative environment. Our local population held a consensus belief that CDMPs would be beneficial for acute pain control. Moreover, it was commonly believed that CDMPs would be safe with few unacceptable side effects for the postoperative period. Contrastingly, while patients believed opioids to hold effective analgesic properties for acute pain they were de-

terred by either first-hand or second-hand experiences of side effects. Those, which were most poorly tolerated, were nausea, hallucinations, and constipation.

There were perceived barriers to the introduction of CDMPs into regular perioperative practice. Most concerns were secondary to its limited prior use and that there is a paucity of clinical data describing its safety and efficacy. The greatest way to overcome concerns of efficacy is to tailor study design to utilize CDMP chemovars that would theoretically provide most benefit in perioperative practice as identified through preclinical and other clinical studies. There were concerns about the effects of CDMPs on the mental health of individuals and in particular those with acute psychotic disorders or those at increased propensity to develop psychoses. Finally, participants were wary of any potential addictive properties of CDMPs, while acknowledging the known risk of opioid by addiction in current perioperative prescribing practices.

Our local population, despite no prior medical background, were surprisingly well informed as to the medical applications of CDMPs. While a small proportion of the participants had either first- or second-hand experience of CDMPs, the role of media in perception of CDMPs cannot be overstated. A commonly described theme was the role of media in public perception of medicinal uses of the cannabis plant. It is clear that the media has a large role in forming the opinions of patients. Many participants cited their knowledge from the media coverage of Billy Caldwell and Alfie Dingley’s use of CBD oil to treat refractory epilepsy and the subsequent rescheduling of CDMPs to permit limited medical use in the United Kingdom.²⁷

With regard to future trial design, this study elicited a number of important patient beliefs on how research should be conducted in this burgeoning field. Most patients trusted that a placebo-controlled RCT would be the best investigation for CDMPs for acute postoperative pain, with the requirement that gold-standard analgesia is provided alongside. Measurement of pain was suggested to continue using widely utilized numerical rating scales. However, some participants noted that it is important to look beyond a linear assessment of pain. As such, using scales that also encompass both affective and cognitive assessment may provide a more accurate representation of treatment effectiveness. In addition, participants believed it to be important to assess side effects of medication use as well as including a quality-of-life assessment.

While every effort was taken to ensure rigorous methodology, there are notable limitations with this study. First, this qualitative study is of a local population of London and may not reflect the beliefs of patients cross the United Kingdom, or other nations. However, every effort was taken to ensure that a representative sample was obtained with a broad age range, varied ethnic background and socioeconomic status, equal gender representation, and both pre- and postoperative patients obtained in the first stage of our PPI program. No restrictions were placed on participant recruitment beyond having conversational English good enough to partake in either an interview or focus group. Moreover, a number of different PPI methodologies were utilized ensuring that we were able to capture their perceptions in both formalized and relaxed settings allowing for in-depth thematic analysis.

This study, in conclusion, presents a qualitative analysis of a local population's beliefs on CDMP prescribing in the postoperative period. Participants had a wholly positive perception of CDMPs for alleviating acute pain and PONV. The results from this study will inform clinical trial protocol development to allow meaningful evaluation of analgesic and antiemetic efficacy of CDMPs.

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Data Availability

Further data are available in the form of original transcripts of interviews. These are available through e-mail correspondence with the authors.

Ethics Approval

The study protocol was approved by the JRCO at Imperial College London. No formal ID was provided, however, they can be contacted for confirmation through JRCO@imperial.ac.uk

Author Contributions

M.M., T.G., B.P., and M.H.S. conceived the study. M.M. conducted the focus group, S.E. conducted the interviews, and M.H.S. conducted the People's Research Café. S.E. and M.H.S. analyzed and interpreted the data. M.M., A.C., and B.P. provided guidance on the study design and analysis. S.E. drafted the article. All the authors read, edited, and approved

the final version of the article. All authors had full access to all of the data in the study.

Author Disclosure Statement

A.C., B.P., and M.H.S. are on the leadership committee of Emmac Life Sciences, a pharmaceutical company specializing in cannabis-derived medicinal products.

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Abbreviations Used

CBD = cannabidiol
 CDMPs = cannabis-derived medicinal products
 HPB = Hepato-Pancreato-Biliary
 PCA = patient-controlled analgesia
 PONV = postoperative nausea and vomiting
 PPI = patient and public involvement
 RCT = randomized controlled clinical trial
 THC = (–)-*trans*- Δ^9 -tetrahydrocannabinol