**A comprehensive patient and public involvement programme evaluating perception of cannabis-derived medicinal products in the treatment of acute postoperative pain, nausea and vomiting using a qualitative thematic framework**

*Running head: Patient & public involvement in cannabis research*

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**Abstract**

**Introduction**

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

**Methods**

A qualitative evaluation was conducted utilising a focus group, semi-structured interviews and a community event. Analysis was conducted via 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 to the known risk profile of opioid use. Decrease in opioid-dependence was agreed to be an appropriate clinical end-point for a RCT 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 sub-populations. Sub-lingual or oral administration was the most acceptable route of administration, with some expressing that inhalation delegitimises 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 anti-emetic efficacy of CDMPs.

**Introduction**

Postoperative nausea and vomiting (PONV) and pain control are important patient-related outcomes(1). PONV whilst important for patient comfort can also result in adverse effects, including aspiration of vomitus, electrolyte imbalances and dehydration, wound dehiscence and reactive haemorrhage. Precise anaesthetic assessment in the pre-operative environment is necessary to reduce the risk of PONV, utilising risk assessment methods such as the Koivuranta score and the Apfel score, to guide anti-emetic management(2). Prescription of anti-emetics reduces the incidence and severity of PONV, however typically they are 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 anaesthetic techniques, systemic pharmacological techniques, in particular opioids, are heavily utilised for acute postoperative pain (5). Opioids, whilst 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’ anaesthetic techniques have shown beneficial effects in achieving adequate control of PONV and acute surgical pain, however are underutilised 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*-Δ⁹-tetrahydrocannabinol (THC), the most widely studied active component of the cannabis plant, demonstrates anti-nociceptive and anti-inflammatory properties via 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 neurorecpetor 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 provide 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 adaption of CDMPs for postoperative use(21). Following change in legislation to legalise CDMPs in the UK on 1st November 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 though in-depth semi-structured interviews, focus groups and a community PPI event. The findings will inform the design and clinical end-points of a double-blinded randomised controlled clinical trial (RCT).

**Materials and Methods**

A qualitative patient and public involvement (PPI) programme was initiated at Hammersmith Hospital, Imperial College London. The first stage described in this paper involves a large focus group (n=14), and separate semi-structured interviews (n=4). The second stage was a community PPI event. The full programme will accompany a clinical trial. All interviews were conducted using local ethical principles and information governance practices. The reporting of the PPI programme 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 via 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 semi-structured approach (Table 1). Minutes were transcribed in real-time.

The first 10 minutes were allowed for introductions, implementation of ground rules and a presentation of a proposed trial design. The proposed trial design detailed a placebo-controlled randomised 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 semi-structured interviews with four participants (Table 1) lasting 30 – 45 minutes each. These sessions began with a 5-minute introduction and presentation of the proposed trial design.

*Community PPI Event*

The community PPI event entitled ‘People’s Research Café’ was conducted at a community centre in London. This utilised a novel research methodology devised by a cross-centre 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 semi-structured 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 cross-matched with the audio to ensure accuracy. The transcriptions were interrogated for relevant discussion. Discussion from the focus group and community PPI event were unable to be recorded due to logistical constraints, however quotations were recorded precisely at time of discussion to ensure accuracy of discussants’ viewpoints. The discussions were independently coded according to theme via a consensus approach by two researchers. The analytical framework was created by assigning codes to different categories. The data was then summarised in a matrix for each category. Emergent themes and degree of consensus and dissent was determined through this process. All analysis was conducted using Microsoft Excel (Microsoft, Redmond, WA, USA).

**Results**

Eighteen participants took part in the first stage of the PPI programme (focus group n=14; M:F=1:1; age range 33-85). Three participants were pre-operative. 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 CDMPs. Of note, 3 participants had personal experience with administration of CDMPs, in particular cannabidiol (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. Whilst 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 delegitimise the medicinal properties of CDMPs:

‘I just think that smoking has so many other associations that it would illegitimise [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 post-operative nausea, exaggerated whilst 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 randomisation with placebo to be acceptable in co-administration 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 amongst 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 emphasised. 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 to 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 towards further investigation of CDMPs for this purpose.

These results are concordant with other investigations into public perceptions of CDMPs. A survey of the UK population demonstrated that 76% of respondents would be open to consuming CDMPs if obtained via a prescription(25). Moreover, there is cross-party support for legalisation of cannabis for medical use indicating that there is likely to be further relaxation of prescribing restrictions in the UK(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, whilst patients believed opioids to hold effective analgesic properties for acute pain they were deterred 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 utilise CDMP chemovars that would theoretically provide most benefit in perioperative practice as identified through pre-clinical 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, whilst 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. Whilst 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 limit medical use in the UK(27).

In regards 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 utilised 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.

Whilst every effort was taken to ensure rigorous methodology, there are notable limitations with this study. Firstly this qualitative study is of a local population to London and may not reflect the beliefs of patients cross the United Kingdom, or other nations. However, every effort was taken to ensure a representative sample was obtained with a broad age range, varied ethnic background and socioeconomic status, equal gender representation and both pre- and post-operative patients obtained in the first stage of our PPI programme. No restrictions were placed on participant recruitment beyond having conversational English good enough to partake in either an interview or interview. Moreover a number of different PPI methodologies were utilised ensuring that we were able to capture their perceptions in both formalised 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 anti-emetic efficacy of CDMPs.

**Supplementary Information**

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