Understanding the Pediatric Patients' Perspective on External Trigeminal Nerve Stimulation (Cefaly®) for Migraine Treatment: A Focus Group Discussion

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ABSTRACT

Purpose: Migraines are highly prevalent among children and adolescents, leading to significant disability. External trigeminal nerve stimulation (Cefaly®) is an emerging alternative treatment for migraine. These non-invasive wearable devices deliver electrical impulses through the skin to reduce pain transmission. Cefaly® has been government-approved for use in adults but has not been formally studied in pediatric-aged populations. We conducted a focus group with three patients (aged 16-17) and a patient partner (aged 18) diagnosed with chronic migraine to investigate perspectives on the Cefaly® device before using it. Involving adolescents ahead of a clinical trial is critical for understanding whether Cefaly® can be integrated into patients' lives and have a meaningful impact in real-world contexts for pain management.

Methods: Participants partook in a 65-minute virtual semi-structured focus group discussion where they were asked open-ended questions regarding their experiences living with chronic migraine and their impressions of the Cefaly® device and barriers to use.

Results: Participants were keen to try Cefaly® but felt it was best suited for home use due to the device's appearance combined with the length of time required per session. Participants described Cefaly® as most helpful as an adjunct for their existing therapies. The device's portability was regarded as advantageous. Participants especially expressed a favourable perception towards the non-invasive nature of Cefaly® and minimal side effects compared to medications and injection-based treatment options.

Conclusion: Adolescents reported a desire to try Cefaly® for treating their chronic migraines. Clinical studies are needed to validate the efficacy of Cefaly® for pediatric populations.

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Background

The prevalence of migraine amongst the pediatric and adolescent population is nearly 1 in 10 (Abu-Arafeh et al., 2010; Victor et al., 2010). Headache is a leading cause of visits to the emergency department and referral to pediatric neurologists (Conicella et al., 2008; Kan et al., 2000). Of those children that experience migraine, a subset will be diagnosed with chronic migraine, meaning that rather than a few episodes, these children will experience frequent headache attacks over a longitudinal period of time. The International Classification of Headache Disorders, 3rd edition (ICHD-3, 2018), defines chronic migraine as "Headache occurring on 15 or more days/ month for more than 3 months." Features of migraine headaches include headache attacks lasting 4-72 hours, pulsating quality, associated nausea, vomiting, light and/or sound sensitivity, and moderate to severe intensity (ICHD-3, 2018).

Leading options to relieve migraine attacks include medications such as Advil (ibuprofen), Tylenol (acetaminophen), triptans or second-generation non-steroidal anti-inflammatory drugs (NSAIDs) such as diclofenac or naproxen (Kacperski et al., 2016). To prevent headaches, common daily-use medications such as topiramate, amitriptyline, or propranolol are frequently used (Oskoui et al., 2019). Unfortunately, these medications come with varying efficacy and side-effect profiles, affecting kidney and liver function in children. For example, NSAIDs such as ibuprofen can cause kidney injury, peptic ulcers, and gastrointestinal bleeding (Kacperski et al., 2016). This is especially problematic for children who are experiencing frequent headaches and therefore taking medications multiple times each week, which can then predispose them to develop headaches from medication overuse. Amitriptyline can cause constipation, fatigue, and dizziness, while topiramate can cause appetite suppression and cognitive slowing (O'Brien et al., 2015). Many pediatric patients may also struggle with compliance in taking daily-use medications (El-Rachidi et al., 2017).

Patients with chronic migraine may also be refractory to pharmacological management, relying on more invasive treatment options such as botox injections or peripheral nerve blocks (i.e., anesthetic injections) of the scalp (Diener et al., 2010; Gelfand & Goadsby, 2014; Hassan et al., 2023; Santana & Lui, 2021). Finding alternative and effective migraine treatments is part of a multifaceted approach to improving pediatric chronic pain management and addressing the misuse of medications such as opioids, which are still widely prescribed in the emergency department as an abortive treatment for migraine (Dodson et al., 2018; Todd, 2017). Even despite evidence suggesting lower efficacy and significantly greater adverse effects, including dependence, addiction, and overdose (Evers et al., 2009; Kelley et al., 2012; VanderPluym et al., 2021).

An emerging alternative to treat migraine is neurostimulation. Neurostimulation is the purposeful modulation of the nervous system to disrupt pain signal transmission. One such therapy is Cefaly®, a wearable medical device that performs external trigeminal nerve stimulation (e-TNS) and is Health Canada and FDA-approved for migraine treatment in adults. Cefaly® is a device meant to be worn on the forehead. It is powered by two AAA batteries that deliver electrical impulses via a self-adhesive electrode on the forehead to stimulate nerve fibres in the upper branch of the trigeminal nerve, which is involved in migraine head pain. This is theorized to induce a sedative effect on the central nervous system, desensitizing the trigeminal nerve. It feels like a buzzing or squeezing sensation on the forehead for the user. Previous adult trials on the Cefaly® device have found efficacy with minimal adverse effects, including sleepiness and a tingling sensation (Chou et al., 2019; Kuruvilla et al., 2022; Magis et al., 2013; Schoenen et al., 2013). Cefaly® offers numerous potential advantages, including that it is a non-invasive device delivered over the skin that can be administered in any location.

More robust research is needed to determine the efficacy of Cefaly® and, importantly, to contextualize and translate these findings to have a meaningful impact on patients' lives. To our knowledge, only two studies have investigated Cefaly® for treating pediatric migraine, with promising results. Esparham et al. (2021) found that Cefaly® was one of the top-performing interventions for treating acute head pain in children following nerve blocks (in the occipital, auriculotemporal, and pericranial nerves), which are significantly more invasive. Cefaly® even outperformed the commonly used migraine cocktails consisting of intravenous anti-inflammatory and anti-nausea medications. Pezzuto (2018) similarly published an abstract on a chart review of pediatric patients who used Cefaly® alone for treating chronic migraine or with Botox treatment. They found that 11 out of 19 patients decreased their headache frequency by at least fifty percent after using Cefaly®.

Based on the findings from the above studies, it is reasonable to further investigate the safety and efficacy of e-TNS with the Cefaly® device for migraine treatment in adolescents. Prior to executing clinical studies, a focus group was conducted for adolescents and a patient partner to prospectively evaluate the Cefaly® device and provide feedback. The objective was to explore pediatric patients' perspectives

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surrounding the utility of Cefaly® for migraine treatment. Little work has been done to explore pediatric concerns regarding headache management. Khayata et al. (2022) recently conducted a focus group to investigate outcomes and treatment preferences in pediatric migraine, and the Cefaly® device aligns with their outlined patient priorities for pain management by providing a non-invasive treatment adjunct that can be used acutely and daily from home, potentially reducing reliance on medications.

Methods

Youth who met the diagnostic criteria for chronic migraine were recruited from the Headache Program at the Stollery Children's Hospital in Edmonton, AB. Convenience sampling was used to recruit participants. Participants were initially approached face-to-face during a clinic visit and were subsequently contacted via telephone and email for scheduling and to complete enrollment. Of the participants initially recruited, two were unable to participate due to time conflicts.

Patients were enrolled in the study if they met the following criteria:

- Ages 12-21 years at the time of enrollment
- A diagnosis of migraine with or without aura by the International Classification of Headache Disorders, third edition (ICD-3) criteria
- Informed consent by a parent or guardian and assent by the pediatric participant
- No prior exposure to or knowledge of the Cefaly® device
- Internet and technology access to join a 1-hour virtual focus group

Study data was managed using REDCap electronic data capture tools hosted and supported by the Women and Children's Health Research Institute at the University of Alberta (Harris et al., 2009). The REDCap model for electronic e-consent was also used, allowing the entire study to be conducted virtually (Lawrence et al., 2020). This entailed participants and their guardians electronically signing the informed consent documents, after reviewing the study thoroughly with the research administrator via telephone. Focus groups were conducted via an encrypted, virtual meeting with a trained interviewer and patient partner present. The focus group was conducted in December 2022 on a weekday evening with participants located at home. Participants were in private rooms with no additional persons. The focus group structure and questions are provided in the supplementary material. Author J.C. is a female medical student at the University of Alberta who led the focus group discussion. The interviewer had no established relationship with any research participants prior to the study's commencement. The participants were aware that J.C. is a medical student researcher working with the study doctor.

Both audio and visual recordings were used for data collection. The discussion was transcribed verbatim

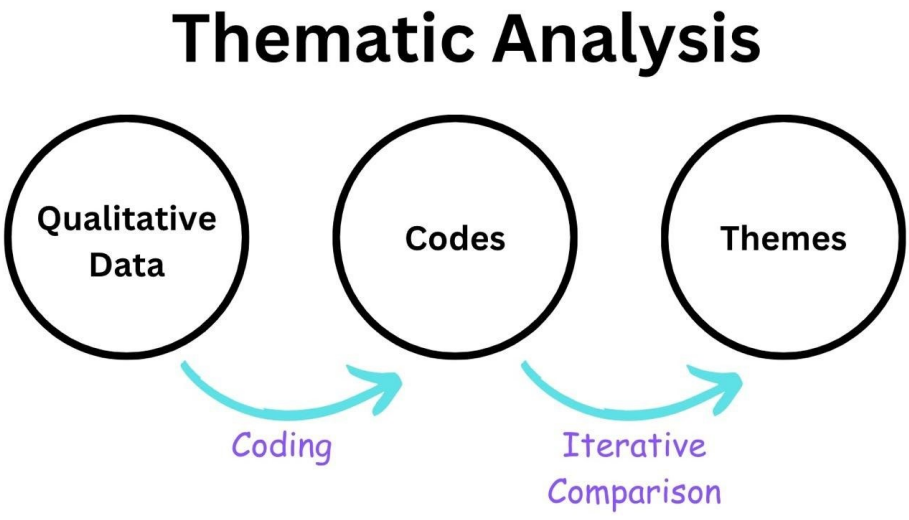

Fig. 1 Thematic analysis methodology for analyzing qualitative focus group data. The discussion was transcribed verbatim using Otter.ai to produce a complete transcript. The transcript was then coded and interpreted using thematic analysis to identify major themes and patterns within the data.

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using Otter.ai, then coded and interpreted using thematic analysis (Fig. 1; Braun & Clarke, 2021) to identify major themes within the data, which required multiple readings of the interview transcript. Verbatim terms (Slevin & Sines, 2000) were used for coding the data, and these codes were then grouped into initial categories, which were further organized into overarching themes after comparing sections of the transcript. To ensure analytic rigour and trustworthiness, the identified themes were reviewed by multiple members of the research team (Braun & Clarke, 2021). Continuous communication within the research team and detailed field notes were essential aspects of this approach (Thomas, 2006). Acknowledging and addressing researcher bias was also taken into consideration throughout the interview and analysis process. This involved having the interview script reviewed by a third-party researcher with expertise in qualitative research. Then, the interviewer rehearsed first with an expert in qualitative research and then with the patient partner to ensure impartiality and asking of open-ended questions. Finally, the patient partner reviewed all results to verify that they accurately represented the participants' views.

Patient Partner Involvement:

The patient partner is an Engineering student at the University of Alberta and lives with chronic migraine. The role of our patient partner was as an active member of the research team. She met with the interviewer ahead of the focus group to provide consultation and feedback on the interview format and questions, including editing the interview script, determining how to best explain the purpose of the focus group and the Cefaly® device to participants, and selecting interview questions. During the focus group discussion, the patient partner was introduced as living with chronic migraine and responded to interview questions to share her experience, helping to facilitate conversation, especially earlier on in the focus group when participants were more reserved. The patient partner's comments were not included in the analysis. Finally, the patient partner reviewed all results, provided feedback, and is an author of this manuscript, collaborating with the research team on multiple presentations and research activities.

Results

Cefaly® treatment was discussed during a 65-minute focus group session consisting of one researcher, three adolescent participants (ages 16-17), and one patient partner (age 18). All participants (N = 3) identified as female. Two participants resided in an urban community; one was from a rural community. All participants had no prior relationship with each other. Conversations about migraine experiences (Fig. 2), treatments, and preferences culminated in discussing the Cefaly® device for migraine treatment and its benefits and drawbacks for regular use. Themes from the focus group discussion centered around Cefaly® for home use, where participants

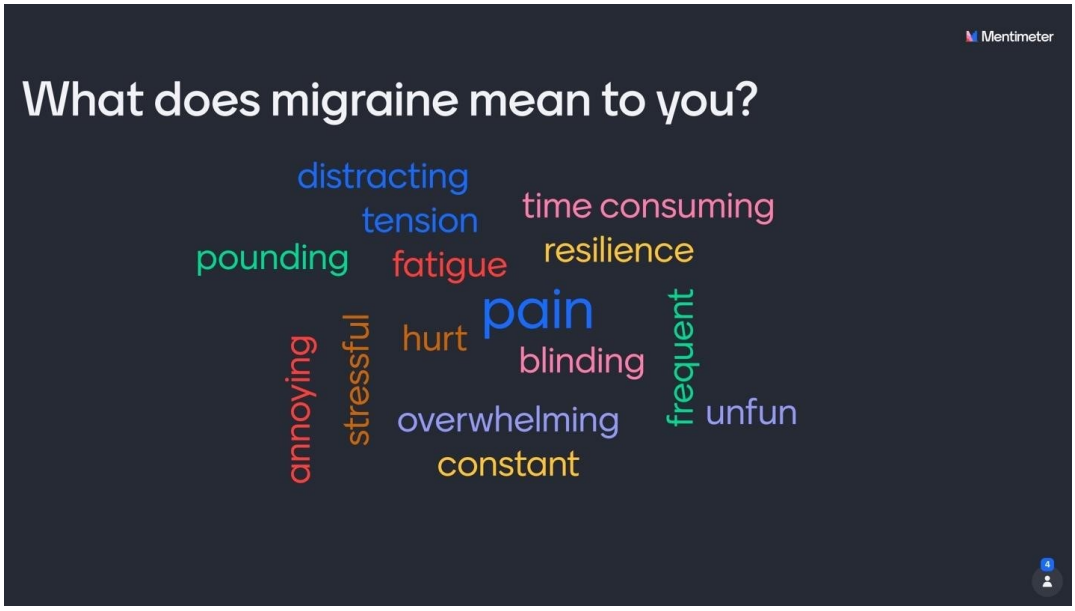

Fig. 2 Word cloud activity performed at the start of the virtual focus group. Participants submitted words on their personal devices via mentimeter.com to generate the following depiction.

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described that they would use Cefaly® most often from the comfort of home due to aesthetic preferences and its time-consuming nature. Participants suggested that using Cefaly® for supplemental treatment was most appealing due in part to the portability and accessibility of the device (Fig. 3).

Cefaly® for home use

The participants were keen to try Cefaly® but commented on the device being most appropriate for home use due to *aesthetic preferences* and *time commitment*.

Aesthetic preferences

Participants described that while it would be positive to use Cefaly® at home, public usage, especially in the context of school, would be undesirable due to the appearance of the device. Participant 1 described this opinion in the following: "it definitely seems like something that would work at home or somewhere else. It just seems like something a little awkward to use at school or in like public when you have a migraine." Participant 2 expressed that "...even if you don't want to bring it to school or sports or things like that as the migraines press throughout the day, you could use that like at the end of the day to relieve all the pressure and stress."

Fig. 3 Cefaly® for home use & supplemental treatment. Analysis of the focus group discussion culminated in two overarching themes to describe pediatric patients' perspectives on the Cefaly® device.

Time consuming

The recommended usage for Cefaly® (20 minutes daily for preventing migraines and 40+ minutes for treating acute attacks) was unappealing to participants for public usage. Patient 2 described the following: "if it had to be 20 minutes, and you forgot or didn't have time to, and it greatly affected overall, that would maybe be something that wouldn't be as appealing." Rather, a 20-minute period before bed or early in the morning were suggested as appropriate times for home use. Patient 3 mentioned this by saying, "I will probably use it like on top of my other treatments as well. So, like if I have time in the morning and then definitely at night."

Cefaly® for supplemental treatment

Rather than a primary treatment, participants described how Cefaly® would complement their existing migraine treatments. Primarily, the *portability* and *accessibility* were noted as positive aspects of the device.

Portability

Overall, participants commented on the small size of the device being beneficial for travel and storage, but one participant noted that the size of a pill bottle (described as a traditional treatment option) is more convenient than a Cefaly® device. In contrast, Patient 2 mentions, "if I did need it, like after a race or something after sports, it is portable, so it's easy to take with you." Others discussed the benefit of being able to take Cefaly® through the airport for use during travel.

Accessibility

Participants described how Cefaly® devices were less intimidating than injections and spoke positively about the at-home usage of the device. Some mentioned that the less invasive nature and minimal side effects made the Cefaly® devices more appealing than traditional treatment options. Patient 2 described the device as "not super scary looking," unlike other migraine treatment modalities, such as injections which require multiple needles. Patient 2 described Cefaly® as an option for different circumstances: "I think it's beneficial that it can be both an attack treatment and a prolonged treatment."

Taken together, patient participants described Cefaly® as a device that is desirable to supplement their other migraine treatment strategies. While there was hesitancy to use the device in public settings, there was consensus that the device would be beneficial at home, with one participant suggesting Cefaly® usage could be integrated into her daily nighttime routine.

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Discussion

The authors acknowledge that a limitation of the current study includes a restricted sample size, as this focus group was a smaller project conducted to gather patient input ahead of clinical study on the Cefaly® device. Traditional migraine research has been directed based on expert consensus rather than stakeholder input. Incorporating patient insight early on and throughout the clinical trial design process is necessary for achieving clinically meaningful results. Participants in the focus group included both urban and rural residing high school youths, of diverse socioeconomic backgrounds and extracurricular interests (including a competitive soccer player, a recreational ballet dancer, and a part-time worker at the local grocery store). Investigations with a larger sample size and heterogeneity of participants across ages, SES, gender, and location are necessary for assuring the generalizability of findings, which was outside the scope of this project. Another limitation of the present study is the potential for researcher bias, which was minimized through the utilization of a patient partner to review results and represent patient views, along with the interview script being revised by a third-party researcher and following established protocols to conducting Thematic Analysis (Braun & Clarke, 2021).

From the focus group discussion with the youth, it was apparent that there were both drawbacks and associated potential benefits to using Cefaly®. As the authors hypothesized, aesthetic preferences are an important factor in adolescents' considerations for using the Cefaly® device. All youth interviewed were high school aged. There was hesitancy to use this device in a classroom setting due to a lack of discretion and time constraints. Instead, the youth described that this device would be more appealing for home usage. In the current study doctor's own clinical practice, many youths will go home early from school for migraine attacks. There is potential usefulness for Cefaly® in treating such migraine attacks at home or in a quiet room at school (ex. school office room).

Another important concern with the Cefaly® device is time considerations. It is suggested in the user manual that Cefaly® be used for daily 20-minute treatments for migraine prophylaxis or 40-120 minutes for treating acute migraine attacks. The time needed for Cefaly® to take effect is important in establishing real-world utility. Many medications used for migraine treatment, such as ibuprofen (Advil®), have an analgesic effect within the hour. Oral medications also have the benefit of being discrete, with medication administration (i.e., by mouth) requiring only seconds. In contrast, the time required to administer Cefaly® is significantly longer. Thus, many youths suggested that Cefaly® would be most appropriate for home usage in the evenings when sitting down for an extended period is feasible.

Beneficial aspects of the Cefaly® device, as discussed by the youth, included that Cefaly® is both reasonably portable and accessible. Cefaly® inside its carrying case is about the size of a tablet. Youth suggested this was a feasible size to bring with them to sporting activities and even while travelling. Additionally, youth described the beneficial nature of Cefaly® being a non-invasive treatment. The youth included in this focus group have a lived experience of chronic migraine, relying on numerous medications and/or injections to treat their head pain. For youth with chronic migraine, who at baseline require therapy for pain control, the non-invasive nature of Cefaly® may be appealing. This therapy can be used alongside other treatment modalities to minimize reliance on medications and/or injections and serve as an adjunct treatment. From clinical experience, and as discussed within the focus group, migraine medications may have undesirable side effects for youth, and many prefer to wean off their medications if possible. As quoted by youth within the focus group:

> "Yeah, so mine definitely gave me a lot of drowsiness. That's why I can only take them at night. Because I found that every single time if I took it at like 9:30, I'd be passed out by 10. They definitely made me a lot more tired. Even like into the mornings. It was hard waking up because I'd always be exhausted."

> "I tried initially. But I forget what the medication is called. But it was a daily medication, and it made me kind of like red in the face all the time. So, and it wasn't really working. So, I just decided to go off of it."

> "We figured that it wasn't having as much of an impact like the medications weren't as helpful as they were in the beginning. And after I was on them for a while it just didn't help us much."

Treatment adherence to pharmacological agents in pediatric migraine is a clinical challenge that is not well studied in the literature. Additionally, literature on pediatric treatment adherence can vary considerably across clinical trial contexts versus real-world usage and patient demographics (including gender, age, socioeconomic status, and cultural background; Gray et al., 2018; Killian et al., 2018; Wadhwani et al., 2020). For example, self-reported medication nonadherence in the CHAMP clinical trial for youth with migraine was low (less than 10%; Hershey et al., 2013). Yet, in

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pediatric chronic conditions, nonadherence to prescribed medication is significantly higher, with some sources indicating 50-60% (El-Rachidi et al., 2017). If effective, wearable devices such as Cefaly® may provide an exciting option for individuals living with chronic pain who have low adherence to medication-based treatments. Wearable and alternative treatments may decrease patients' reliance on medications and/or serve as an add-on to control refractory pain. Only two research studies that investigated Cefaly® for pediatric patients could be identified. Despite this, youth are using Cefaly® and other wearables to manage pain. In the author's experience, youth admitted for treatment at the Stollery Children's Hospital in Edmonton, AB, Canada were found using Cefaly® off-label to treat their migraine attacks. Cefaly® is a non-invasive intervention which does not require intravenous access or injections and, therefore, can be administered without medical personnel. Given these promising findings, including those from Esparham et al. (2021), who retrospectively found Cefaly® to be an efficacious intervention for treating acute head pain in pediatric populations, clinical trials are warranted.

From the current focus group results, it is suggested that a timeframe of 60 minutes may be optimal for future studies investigating Cefaly® for acute migraine attacks in adolescents. This timeframe may balance the time-consuming nature of the treatment session with concerns regarding efficacy and is in agreement with suggestions resulting from the TEAM trial (Kuruvilla et al., 2022). It is also suggested that future research trials allow youth to use the Cefaly® device as an adjunct treatment and in a home setting as much as possible to mimic youths' ideal usage of Cefaly® in the real world. The discrepancies between treatment adherence in controlled clinical settings versus real-world contexts necessitate patient engagement for effective treatment planning. Notably, recruiting patient partners for future clinical studies is suggested to ensure real-world applicability in the lives of pediatric patients. Wearable medical technologies are a compelling new avenue of exploration for use in pediatric patients, and future patient-led treatment discussions may improve adherence in pediatric populations.

Conclusion

The focus group discussion with patients and a patient partner with lived experiences of chronic migraine provides valuable insights as to the potential utility of Cefaly® for treating migraine in adolescents. Youth expressed a desire to use the device primarily at home due to aesthetics and time preferences. Focus group participants saw Cefaly® as a supplemental treatment that could complement their existing migraine management strategies. The non-invasive nature of Cefaly® was particularly appealing to youth, as it could reduce their reliance on medications and injections. The importance of designing future studies to mimic real-world applications in the lives of youth with chronic pain was emphasized. Wearable devices like Cefaly® have exciting potential to improve the quality of life for adolescents with chronic migraine.

Statements and Declarations

Conflicts of Interests Statement

On behalf of all authors, the corresponding author states that there is no conflict of interest. No financial support for the research, authorship, and/or publication of this article was received from Cefaly® Technology.

Authors' contributions

J.C. led study design, data collection, and wrote the main manuscript text. K.W. led qualitative analysis and wrote the methods section. P.M. wrote the abstract and edited the main text. T.N. was the patient partner, who provided consultation throughout study design, was present during the focus group to facilitate group discussion, and reviewed the analysis, providing feedback. T.R. was the principal investigator and study doctor who directed and oversaw all aspects of the research project. All authors reviewed the manuscript and approve of its publication.

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Ethics approval

This study was approved by the University of Alberta Health Research Ethics Board (reoffice@ualberta.ca). Ethics ID: Pro00122532.

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