

BURDEN OF SEIZURE CLUSTERS ON PATIENTS WITH EPILEPSY: SURVEY OF PATIENT PERSPECTIVES AND PREFERENCE

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INTRODUCTION

- Seizure clusters occur in many patients with epilepsy, despite treatment with antiepileptic medications¹.
- Rescue medications must be designed so patients, or their caregivers, can access and successfully administer a drug expediently during a medical crisis wherever it occurs.
- Diazepam Buccal Film, Aquestive Therapeutics, is an oral rescue therapy intended for management of refractory patients with epilepsy on stable regimens of antiepileptic drugs (AEDs), who require intermittent use of diazepam to control breakthrough or cluster seizures (CS), as well as acute repetitive seizures (ARS).
- The expected convenience and ease of use of Diazepam Buccal Film has the potential for major contributions to patient care (MC-to-PC).
- To address the potential MC-to-PC of Diazepam Buccal Film, Aquestive initiated an independent, third-party survey of 101 patients with epilepsy who experience ARS regarding their experiences with cluster seizures and rescue therapies.

OBJECTIVES

- The primary objective of this study was to assess the potential MC-to-PC of Diazepam Buccal Film through patients' perspectives regarding:

- Convenient treatment location
- Patient comfort
- Reduced treatment burden
- Advances in ease and comfort of drug administration
- Potential for self-administration.

METHODS

- Aquestive initiated an independent, third-party survey consisting of a 20-minute online questionnaire completed by 101 patients.
- To qualify for the survey, the patients had to:
 - Verify they were 18 years of age or older;
 - Choose "seizures" from a list of medical conditions as one that they had been diagnosed with by a medical professional
 - Confirm that they have "experienced repetitive or cluster seizures".
- Patients were then asked a series of 16 questions about their cluster seizure treatment prior to the introduction of treatment options. These questions centered around the patients' experiences, concerns, and aspirations for improved treatments.
- For the second part of the survey, patients were shown a brief video of packaging similar to Diazepam Buccal Film and packaging similar to diazepam nasal spray. After watching the video, patients were then asked an additional set of questions focused on their preference between the two treatment options. The survey included both multiple choice and free response questions.
- Median time to complete survey 19.4 minutes

ANALYSIS

- Data are summarized using descriptive statistics with no formal statistical testing performed.

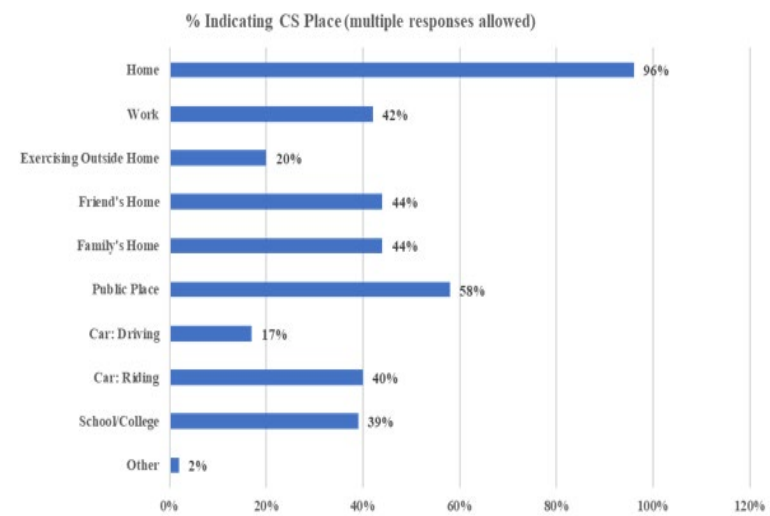
RESULTS

PARTICIPANTS DEMOGRAPHICS

- N = 101 Qualified Cluster Seizure (CS) Patients
- Nationally representative sample
- Diversity
 - 60% female; 40% male
 - 17% 18-25 years of age
 - 38% 26-40 years of age
 - 16% 41-50 years of age
 - 22% 51-60 years of age
 - 8% 61-65 years of age

PARTICIPANTS EXPERIENCES, CONCERNS AND ASPIRATIONS

Figure 1: Places CS Have Occurred



96% of respondents have experienced CS occurrences in their home setting, which was the most common location of CS occurrences. However, a large proportion of respondents have also experienced CS occurrences outside of their homes, including 58% in public places and 44% in the homes of friends or family members (Figure 1).

RESULTS (Cont.)

Figure 2: Level of Worry: CS in Public Place

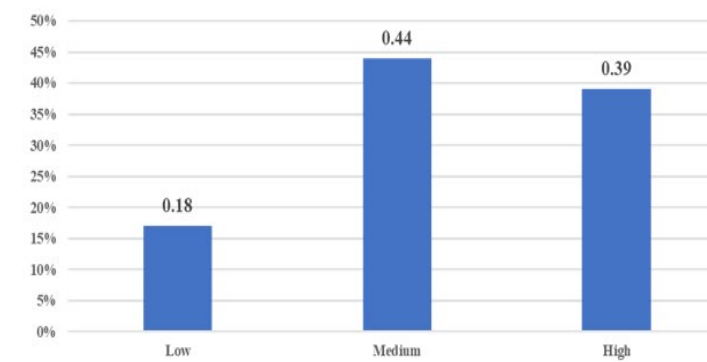
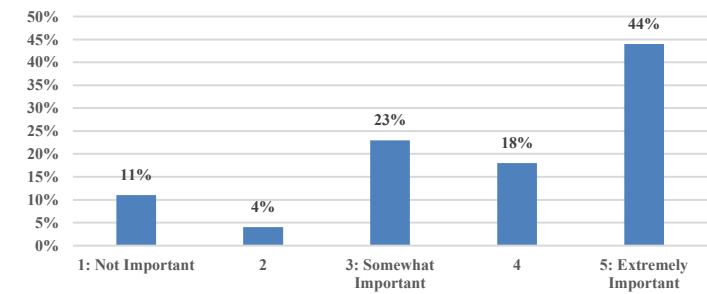


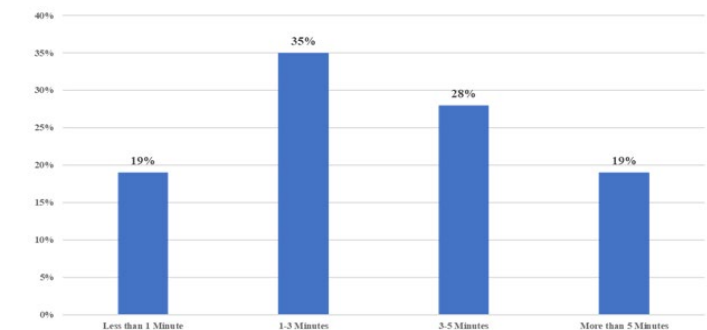
Figure 3: Importance of Having CS Med Close at all Times



Eighty-three percent (83%) of respondents indicate a medium to high level of concern of having a CS in a public place (Figure 2) and 85% felt it was at least "somewhat important" to have their CS medicine close to them at all times, and 62% felt it was important to extremely important (Figure 3).

A majority of patients (82%), felt it was important to take their rescue medication within 5 minutes of CS onset (Figure 4) and accessibility, timeliness, and simplicity of CS medications were most important features to the vast majority of patients surveyed (Table 1).

Figure 4: Desired Time to CS Medication Dose



RESULTS (Cont.)

Table 1: Survey Questions Addressing Accessibility, Timeliness and Simplicity of CS Medications

% Indicating	1: Not at all Important	2	3: Somewhat Important	4	5: Highly Important	Top 2 Box
Ability to have the repetitive seizure medicine with me at all times	3%	7%	20%	26%	45%	71%
Ability to take the medicine as quickly as I possibly can when I need to	3%	4%	14%	28%	51%	79%
Ability to take the medicine in a way that is simple for me	2%	2%	13%	23%	60%	83%
Ability to take the medicine no matter where I am and what I am doing	3%	2%	14%	23%	58%	81%
Ability for me to take the medicine myself, versus someone else having to give it to me	5%	3%	22%	28%	43%	71%

TREATMENTS COMPARISON

Table 2. Survey Questions Addressing Which Medication Respondents Would Request Physicians Prescribe

% Choosing	Strongly Prefer Nasal	Prefer Nasal	No Preference	Prefer Film	Strongly Prefer Film	Film Pref.
44. If both medicines worked just as well at stopping my repetitive seizures, I would prefer my doctor prescribe me:	6%	7%	16%	21%	50%	71%
45. Likelihood of me asking my doctor if I could switch from the current medicine I have for repetitive seizures to one of the new products:	7%	8%	20%	27%	39%	66%

- When asked to describe the ideal medication for treatment of repetitive seizures, respondents overwhelmingly cited convenience to carry and administer. The most frequent comments included a medication that dissolves in the mouth without needing access to water and something sleek and discreet that can fit in a pocket.
- After watching a video comparing film and nasal spray medication packaging, 80% of respondents indicated they would "usually" or "always" have the film at arm's length compared to 38% for the nasal spray.
- When surveyed across a number of attributes including ease of having at arm's length, likelihood of having medication when needed, privacy, avoidance of embarrassment, independence, and overall convenience, the vast majority of respondents "preferred" or "strongly preferred" film versus the nasal spray
- At the conclusion of the survey, when asked "If both medicines worked just as well at stopping my repetitive seizures, I would prefer my doctor prescribe me X", 71% of the respondents preferred or strongly preferred the film, while only 13% of the respondents preferred or strongly preferred the nasal spray (Table 2).

CONCLUSIONS

- Of the 101 patients surveyed, a significant number (83%) indicated a medium to high level of concern regarding having a cluster seizure (CS) in a public place.
- Most respondents (85%) believe always having rescue medication close by is at least "somewhat important".
- Despite 76% of respondents expressing concern with regards to having rescue medication within arm's length when not at home, only 34% always carried their rescue medication at arm's length outside the home.
- 80% of respondents indicated they would usually or always have the film product within arm's length. In comparison, only 38% told they would usually or always have the nasal spray product within arm's length.
- 89% of respondents believe a buccal film would fit in their pocket, while 80% indicated they would need an additional carrying case to carry the nasal spray.
- 72% of respondents indicated they prefer or strongly prefer the buccal film when asked about the "likelihood of having the medicine with me when I need it." In contrast, only 11% of respondents indicated they prefer or strongly prefer a nasal spray.
- When given the statement "my feeling a greater sense of independence," 67% of respondents preferred or strongly preferred the buccal film, while 7% preferred or strongly preferred the nasal spray.
- This survey results strongly confirm the need for highly portable rescue medications, in proximity, with the potential for self-administration where and when they are needed.
- These survey results substantiate the significant contribution to patient care that Diazepam Buccal Film offers.

REFERENCES

1. Laxer, K et al., *Epilepsy & Behavior*, 2014; 37:59-70

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DISCLOSURES

Carla Buan, Gary Slatko, and Ayman Kafal are employees of Aquestive Therapeutics, Inc.