ABSTRACT

Background: In 2016, Melbourne was struck by the world’s largest and most devastating epidemic thunderstorm asthma (ETSA) episode. While affected individuals displayed worsened short-term asthma control, little is known about their longer-term natural history, nor about interventions that restore control.

Objective: We assessed the asthma symptomatology and related behaviours of ETSA-affected individuals through a single-centre prospective 5-year longitudinal study. We embedded an open-label observational trial investigating the role of grass pollen sublingual tablet (Oralair) allergen immunotherapy in improving asthma and allergic rhinitis symptoms.

Methods: Allergic rhinitis symptom severity, frequency of asthma symptoms and inhaled corticosteroid usage were assessed via questionnaire yearly. In 2018, a subgroup of participants was enrolled in an observational study of Oralair treatment compared to control. The active group received Oralair from 2019 to 2021; both groups were followed-up for 5 years. Subgroup analyses were performed for participants with complete datasets, and who completed the trial per-protocol.

Results: Year-on-year data across 5 years was available for 30 participants. The rate of persistent asthma symptoms declined from 37% to 7% in 2016 to 2021. Only 10%–27% of participants reported being completely asymptomatic in any given year. The inhaled preventer prescription rate was 67%, with only 35% being adherent. Twenty-seven participants with available data completed the Oralair trial per-protocol. No significant difference was noted between control and active groups for allergic rhinitis symptoms or asthma control, although the Oralair group saw a significant improvement in asthma control comparing 2019 with 2021.

Conclusion: This is the longest documented follow-up of ETSA-affected individuals. Five years following sentinel event, there was progressive reduction but some persistence in asthma symptoms. Oralair allergen immunotherapy did not further improve allergic rhinitis or asthma symptoms compared to control, but there were no further ETSA events to test a protective effect during the study period.

Keywords: Asthma; Environment; Epidemics; Natural history; Pathophysiology; Public health
INTRODUCTION

Epidemic thunderstorm asthma (ETSA) refers to an observed increase in cases of acute bronchospasm following a local thunderstorm event. The world’s largest and most devastating ETSA occurred in Melbourne, Australia on Nov 21, 2016 [1]. This resulted in over 3,500 Emergency Department presentations of asthma attacks and 10 deaths. Little is known about the natural history of asthma symptoms in individuals affected by such a catastrophic event. Our group has previously shown that certain individuals experience a pivotal change in asthma trajectory with both loss of asthma control, and persistence of de novo asthma, up to 3 years after the initial event [2]. Whether this phenomenon extends beyond 3 years remains unclear.

Furthermore, the use of a commercial 5-grass sublingual immunotherapy (SLIT) tablet (Oralair, Stallergenes Greer, Baar, Switzerland) in individual with seasonal allergic rhinitis (some of whom also had a doctor-diagnosis of asthma) appeared to be protective against ETSA compared to those treated with only pharmacotherapy [3]. It remains to be determined if Oralair therapy in this cohort of individuals would have any impact on their asthma and rhinitis symptomatology beyond the ETSA event.

In this single-centre prospective longitudinal study, we assessed the symptomatology, behaviours and healthcare utilisation of individuals at 12, 24, 36, 48, and 60 months after the 2016 thunderstorm asthma event, and the effect of Oralair therapy on asthma and rhinitis symptoms in a subgroup of this cohort.

MATERIALS AND METHODS

Part of the methodology used in this study has been previously described and are summarised here [2]. Individuals who had presented to our health service Emergency Departments with ETSA in 2016 were eligible for recruitment. Consenting individuals were administered a structured telephone questionnaire (Supplementary Material 1) in December of 2017–2021. Specific questions regarding asthma symptomatology, preventer usage, asthma action plan ownership, and healthcare utilisation in the preceding 12 months were included. At the end of the questionnaire, individuals were given the option to participate in ongoing research and those who declined were not contacted subsequently. Those who agreed were contacted the following year, and attempts were made to contact nonresponders in subsequent years. The preferred method of administering the questionnaire was through response over phone; however, other acceptable methods included reply-paid questionnaires sent via mail or online survey, which could be emailed to participants for completion. Patients who declined to consent, were uncontactable, or did not respond to the mailed questionnaire were excluded from the analysis.

Asthma symptomatology was assessed based on frequency of symptoms reported, and responses to the asthma control test (ACT). Frequency of asthma symptoms (wheezing, coughing, shortness of breath, and chest tightness) were categorised into ‘persistent,’ ‘frequent episodic,’ ‘infrequent episodic,’ or ‘asymptomatic’ depending on their average frequency over the last 12 months. ‘Persistent’ was defined as having symptoms ≥ once a week; ‘frequent episodic’ as having symptoms > once a month but < once a week; ‘infrequent episodic’ as having symptoms ≤ once a month, with ‘asymptomatic’ reporting no symptoms.
The ACT is a series of questions which assesses an individual's asthma control over the past 4 weeks. The scores range from 5 (worst possible control of asthma) to 25 (optimal asthma control), and can be further categorised into ‘well-controlled asthma’ (score > 19), ‘not well-controlled asthma’ (score 16–19) and ‘poorly-controlled asthma’ (score <16) [4].

Allergic rhinitis was assessed with the allergic rhinitis and its impact on asthma (ARIA) grading of severity [5] and calculated based on the responses to questions evaluating the perceived impact of rhinitis on activities of daily living, and ranged from 0 (no impact) to 4 (highly impacted).

In the 2018 follow-up, participants were offered the opportunity to participate in an observational Oralair SLIT study. Eligibility to participate were as follows (1) history of seasonal allergic rhinitis, (2) positive skin prick test (≥3 mm above negative control) to ryegrass pollen, and (3) no prior history of allergen immunotherapy. Baseline assessments for participants included allergy skin prick tests, ryegrass serum specific IgE, spirometry and exhaled nitric oxide. Outcome measurements were ARIA rhinitis severity and ACT questionnaires. Participants indicated their preference to either receive Oralair SLIT or be observational controls in the subsequent follow-up. Group assignment was not randomised but instead based on patient preference. Oralair SLIT daily was initiated in the active group in 2019, 2020 and 2021 for 4 months each year before the November month of peak grass pollen activity in Melbourne, as in the study by O’Hehir et al. [3]. The observational control group continued with their usual rhinitis and asthma medications and management. Oralair SLIT and observational controls were followed up in December 2019, 2020, and 2021, receiving the same assessment as previous years at these intervals. Available data from these groups were analysed on a per-protocol basis.

Analysis
IBM SPSS Statistics ver. 28.0 (IBM Co., Armonk, NY, USA) was used for all statistical analyses. The Shapiro-Wilk normality test was used to assess the distribution of data. Numerical data were summarised using mean, median, standard deviation or interquartile range depending on their distribution. Mann-Whitney U test and Wilcoxon signed-rank test were used to analyse independent groups and paired sets of data respectively. Categorial data were presented as number (%) and analysed using the chi-squared test. A p value of less than 0.05 was considered statistically significant.

The study was approved by Eastern Health Human Research Ethics Committee (HREC) approval number: E09-2018.

RESULTS

Response rate
From an original 262 individuals who indicated willingness to participate in ongoing research in the 2016 questionnaire, 243 were contacted again in 2017. Two hundred eight (86%) individuals completed the questionnaire in 2017, with 11 participants withdrawing consent, and 24 participants unable to be contacted. In the following year 2018, a further 11 participants withdrew participation, and 57 individuals were uncontactable, leaving 164 (71%) completed questionnaires from a total of 232 individuals where contact was initiated. In 2019, 112 (51%) completed questionnaires were returned out of 221 attempted contacts, and of the remainder 11
participants declined further contact, and 98 were not able to be contacted (Fig. 1). From 2020 onwards, only participants enrolled in the open-label immunotherapy substudy (n = 43) were contacted for follow-up. In 2020, 32 questionnaires (74%) were returned, with 11 participants uncontactable that year. In 2021, 35 participants (81%) were successfully contacted and questionnaires returned, with 8 individuals being uncontactable (Fig. 2).

Subgroup analysis
Our analysis focused on the subgroup of participants (n = 30) with available, complete, year-on-year data for 5 consecutive years. These participants are drawn from the cohort of 43 individuals who were enrolled for further follow-up in 2019 in the Oralair trial, which was drawn from the cohort of all participants enrolled in the original 2016 study, excluding those who declined further participation.

The mean age of this group was 39 ± 15 years, with 63% being male. 43% of these individuals had ‘doctor-diagnosed’ asthma prior to ETSA event in 2016, with 57% having no prior diagnosis. This subgroup of participants is not demographically different from the cohort analysed at the 3-year mark of the ETSA follow-up study in 2019 (Table 1), which itself was not different to the original 2016 cohort [6]. In 2016, the mean age of the participants was 32.2 ± 19.3 years, with 58% being male. In 2019, the mean age of the participants was 33.1 ± 19.4 years, with 60% being male [2].

Symptomatology
The frequency of asthma symptoms at yearly intervals is presented in Fig. 3. There was no significant difference in the groups over the 5-year span. Following ETSA event in 2016, the

**Fig. 1.** Consort diagram of original cohort from 2016 to enrolment in Oralair immunotherapy substudy in 2019.
A 5-year study of epidemic thunderstorm asthma patients

number of participants who reported persistent asthma symptoms gradually declined year-on-year, from 11 individuals (37%) in 2017 down to 2 (7%) in 2021. Every year, however, the majority of individuals still reported having asthma symptoms at least once a year, with only 8 (27%) being completely asymptomatic in 2021, 5 years after the sentinel event.

Asthma preventer prescription and adherence, asthma action plan ownership, and healthcare usage for asthma

In 2021, 67% (n = 20) of participants reported being prescribed an inhaled corticosteroid (ICS) preventer for asthma. Those who described higher frequency of asthma symptoms (frequent and persistent symptom groups) had a higher preventer prescription rate of 86% compared...
with the 61% prescription rate of those who described lower frequency of asthma symptoms (asymptomatic or infrequent). Overall, only 35% of all individuals prescribed an ICS preventer reported adherence to the prescriptions (usage ≥ 5 days a week in the given year).

One-third of individuals reported having an asthma action plan in 2021. Twenty percent of participants reported healthcare utilisation in the context of asthma at any point in the past year, all being nonurgent general practitioner visits for review of asthma control.

Oralair analysis
From the 135 participants who initially expressed interest in substudy participation in 2018, 111 were able to be contacted, and 43 participants enrolled. Twenty-four participants were unable to be contacted following initial expression of interest, and 68 participants who were contacted for assessment either declined further participation or were deemed ineligible as they were not grass pollen allergic or had undergone immunotherapy outside the study.

Initially, from the 43 enrolled, 20 and 23 participants were assigned to the active and control groups respectively. Between 2019 and 2021, 5 participants in the active group discontinued medication were reassigned to the control group—2 due to side effects from medication, and 3 due to lack of adherence to daily medication and follow-up. A further 2 individuals in the active group were lost to follow-up, along with 6 individuals in the control group. As of November 2021, the active group had 13 contactable participants, and the control group 22.

Subgroup analysis
Our subgroup analysis focused on the 27 individuals for which there exists 3 consecutive years of data, and were not reassigned from active to control during the period of the study. This included 13 individuals in the active group and 14 in the control group. The mean age of the 27 participants included was 38 ± 14 years, with 59.3% being male.

The median (interquartile range, IQR) ACT score (ACT score) amongst control group participants in 2021 was 21 (16.75–23.25), whereas the ACT score amongst Oralair group participants was 22 (18.00–24.00). No significant difference in median ACT score was noted between active and control groups in any individual year. Analysis within the active and control groups over time displayed no significant difference between the ACT scores of the control group between 2019 and 2021. The control group participants had a median (IQR)
ACT of 18 (17.0–22.0) in 2019, compared with a median ACT score of 21 (17.0–23.0) in 2021 ($p = 0.270$). A statistically significant difference was noted, however, when comparing the median [IQR] ACT scores of the Oralair group in 2019 (21 [17.0–22.0]) and 2021 (22 [21.0–24.0]) in 2021 ($p = 0.018$) (Fig. 4).

Of the 6 participants who reported healthcare utilisation in the context of asthma in 2021, 4 were in the control group, with 2 in the Oralair group. All healthcare visits were nonurgent general practitioner visits for review of asthma control.

Over the 3 years, the majority of participants continued to report symptoms of allergic rhinitis ranging from mild to moderate/severe ARIA severity score (Table 2). In the Oralair group, those with moderate/severe rhinitis symptoms declined from 77% to 46% from 2018 pre-treatment baseline to 2021, whereas those in the control group, moderate/severe rhinitis declined from 79% to 64% over the same time period. No significant differences were noted between the active and control groups in any given year, nor were there any significant differences within the groups across years. Analysis of ARIA severity score demonstrated a median (IQR) of 2.0 (1.0–3.0) impacts of allergic rhinitis in both 2019 and 2020, and 1.0 (0–3.0) in 2021, with no significant difference in severity noted between active and control groups in any year.

**Fig. 4.** Asthma control test (ACT) score of Oralair and control participants reported at yearly intervals from 2019–2021. NS, not significant.

**Table 2.** Severity of allergic rhinitis by year

| Group          | ARIA severity score | 2018 | 2019 | 2020 | 2021 |
|----------------|---------------------|------|------|------|------|
|                | 0                   | ≥1   | 0    | ≥1   | 0    | ≥1   |
| Oralair (n = 13) | 3 (23)              | 10 (77) | 3 (23) | 10 (77) | 3 (23) | 10 (77) | 7 (54) | 6 (46) |
| Control (n = 14) | 3 (21)              | 11 (79) | 1 (7)  | 13 (93) | 3 (21) | 11 (79) | 5 (36) | 9 (64) |

Values presented as number (%)

Allergic rhinitis and its impact on asthma (ARIA) severity score: no symptoms/mild = 0, moderate/severe≥1.

No significant difference between groups in any year nor between years for groups.

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DISCUSSION

In this study, we report the longest follow-up of individuals following Emergency Department presentation after an ETSA event, assessing ongoing symptomatology and behaviours. We found that even 5 years post sentinel event, the overwhelming majority of individuals—in the context of a cohort where 40% of individuals reported having had no asthma symptoms in the 12-months prior to ETSA event—still reported ongoing asthma symptoms of varying levels. Low ICS preventer adherence may have been a contributor to ongoing symptomatology—a feature that warrants concern given that poor ICS usage has been shown to be an independent risk factor for hospital admission following ETSA [7].

Worryingly, individuals within the subgroup of ‘no asthma’—both no formal asthma diagnosis prior to 2016 and no symptoms suggestive of undiagnosed asthma—also continued to report ongoing asthma symptoms after 5 years. This reinforces the notion that a catastrophic ETSA of the scale and severity as in 2016 Melbourne event may lead to the occurrence of *de novo* asthma in people without pre-existing history of airways hyperreactivity, and that this remains persistent long term, as suggested in our previous studies [2, 6].

The pattern of symptomatology shown by the data reveals that while asthma symptom frequency was initially high after the sentinel event—with almost half of the cohort reporting experiencing symptoms at least once a month—over time, symptom frequency trended towards becoming less frequent. Of note, the number of individuals who reported experiencing persistent (more than once weekly) asthma symptoms declined steadily over this 5-year period. In this smaller cohort, no correlation was noted between past asthma status and the frequency of natural history of symptoms 5 years post-ETSA event, in contrast to our previous finding that those with a prior doctor-diagnosis of asthma were less likely to be asymptomatic at the 3-year mark [2].

It is important to note that due to the unpredictability of ETSA events, there has not been a comparable event since 2016 that may serve as a rechallenge to ETSA susceptible individuals. It would be of value to further follow-up and assess the symptomatology of these individuals if another such event were to occur.

Open label Oralair observational study

Despite participants in the active group being treated per-protocol with 3 years of Oralair immune desensitisation therapy, our results showed little significant difference between either the symptoms or severity of both asthma and allergic rhinitis in participants of the active and control groups. A significant difference was observed between the ACT scores of the Oralair group when comparing scores in 2019 and 2021 respectively (median ACT 21 in 2019 compared with 22 in 2021, \( p = 0.018 \)). This score could represent an overall improvement in perceived asthma control over the 3-year course of therapy, during the timeframe where a similar improvement was not present in analysis of the control group. However, given the minimally important difference for ACT is unknown—with one study postulating 3 points [8]—it is unknown whether such a result would translate into clinical significance. Another factor may be that the ACT score was already relatively high in this cohort (all > 19, indicating well-controlled asthma), and there may not have been sufficient room for further improvement to demonstrate a statistical significance with the numbers of participants in this study.
The overall burden of disease for allergic rhinitis remained high in both active and control groups with the significant respondents still reporting moderate/severe symptoms on a yearly basis. While statistically insignificant, there was a greater reduction in percentage of Oralair participants reporting moderate to severe allergic rhinitis compared with control in 2021. Notably in 2019, the number of participants reporting moderate/severe allergic rhinitis symptoms in the control group increased compared with 2018 baseline, whereas no such increase was noted in the Oralair treatment group after the first year of treatment. This is in line with current literature that shows Oralair desensitisation immunotherapy to be an effective and well tolerated treatment for grass pollen allergic rhinitis \[9, 10\]. Another factor may have been that outcome assessment for allergic rhinitis in this study was the ARIA severity score. This may not have been sensitive enough to symptomatic benefit in rhinitis treatment compared to other outcome measures such as the visual analogue scale \[11, 12\]. It is also possible that the massive allergen challenge/provocation associated with the ETSA event may have rendered those affected relatively refractory to allergen immunotherapy. Nevertheless, our results indicate that Oralair has the potential to improve allergic rhinitis symptoms in this ETSA cohort and could be indicated in the clinical management of individuals with a history of ETSA.

Oralair has been shown to have an opportunistic benefit in protecting certain individuals from thunderstorm asthma \[3\]. As there was no ETSA event during the 3 years of Oralair treatment, we were not able to show benefit of Oralair SLIT in protecting against thunderstorm asthma. Given the increased risk of severe and life-threatening ETSA in those with current, in particular poorly-controlled, asthma \[13\], it would be useful to conduct further research and follow-up in this group of ETSA-affected individuals to gain better insight into the longer-term benefits of Oralair for this cohort.

Limitations
Overall, both arms of our study are limited by small sample sizes, primarily due to high rates of participant attrition over time. The reason for high attrition may relate to the preferred method of contact being via phone or email, as opposed to an in-person appointment or assessment. Other reasons may include the nature of the study demographic: with a mean age of 40, a high proportion of participants are young working professionals with family commitments who are relatively healthy apart from asthma and allergic rhinitis and in general, do not have high healthcare utilisation. Another consideration is the geographic mobility of these individuals, with a not insignificant number of participants reporting having moved either interstate or overseas, further increasing the difficulty of contacting each individual.

In particular, the Oralair substudy was limited by the effects of coronavirus disease 2019 (COVID-19), and the numerous periods of city-wide lockdown experienced in Melbourne. The most obvious challenge this posed was a reduction in the capacity of all health services in the state to provide in-person appointments and follow-up for nonessential reasons. In turn, trial participants were unable to be assessed in person, and therefore the reliance on phone or email contact was further augmented. For specific individuals, as a result of being uncontactable, they were unable to access the trial medication altogether in 2020 or 2021, reducing the number of participants who completed the trial per-protocol. Another change that COVID-19 brought to Melbourne—especially given extended periods of lockdown—was an exodus of people from the metropolitan area to regional areas or even interstate in Australia. This level of mobilisation would have an additional impact on the challenges
faced in attempting to contact participants for research purposes, amplifying the level of participant attrition faced in our study.

In conclusion, this is the longest documented follow-up of 30 ETSA-affected individuals for 5 years following sentinel event. There was persistence of moderate to severe rhinitis symptoms and progressive reduction but some persistence in ongoing asthma symptoms. Oralair allergen immunotherapy did not further improve allergic rhinitis or asthma symptoms compared to observational control in this small cohort, but there were no further ETSA events to test a protective effect during the study period.

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SUPPLEMENTARY MATERIAL

Supplementary Material 1 can be found via 10.5415/apallergy.2022.12.e38

Supplementary Material 1

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