Multicentre experience of home omalizumab treatment for chronic spontaneous urticaria

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ABSTRACT

Introduction Due to perceived risk of anaphylaxis, home treatment with omalizumab has been limited. Within the UK, most centres administer omalizumab in a hospital setting. However, the reported prevalence of anaphylaxis is low and in December 2018 home treatment became licensed. A home treatment pathway was previously reported by one UK centre, and this update describes three UK centres' experience of home omalizumab treatment.

Methods The medical records of omalizumab patients were retrospectively reviewed.

Results A total of 137 adult patients have received home omalizumab treatment; home treatment duration 0–44 months. There was no increase in adverse effects seen in patients treated at home. There were no reported adherence issues and no reduction in efficacy. Patients report they prefer home treatment due to increased flexibility and reduced impact on daily life/work.

Conclusion Home treatment with omalizumab is a safe and effective alternative to hospital administration.

INTRODUCTION

Omalizumab is a recombinant DNA-derived humanised monoclonal antibody that selectively binds to human IgE and is licensed for use in patients with allergic asthma and chronic spontaneous urticaria (CSU).

Omalizumab is administered via subcutaneous injection for both indications, the majority of which are given within hospital outpatient departments or day-case units. This can lead to clinic capacity problems, especially with increasing patient numbers, and increases the cost of the patient's treatment pathway. Previously, concerns regarding anaphylaxis, adherence and efficacy have limited home self-administration of omalizumab.

In December 2018, home self-administration of omalizumab became licensed. Prior to this license change, three immunology centres within the UK developed home treatment pathways for patients with CSU, one of which was described in an earlier publication.[1] This update describes all three UK centres' experience of self-administration or carer administration of omalizumab at home for CSU and the pathways used to supply omalizumab.

METHOD

The medical and pharmacy records of all patients with CSU treated at home with omalizumab at all three centres were reviewed. Data were collected and collated on number of patients, duration of home treatment, adverse events including any cases of anaphylaxis, and any perceived problems with adherence. The follow-up management processes of all three centres were also reviewed. Within this article, hospital-treated patients are those who continue to receive omalizumab within the hospital setting.

RESULTS

Across the three centres, a total of 137 adults have been treated at home with omalizumab to date. There were no paediatric patients. The duration of home treatment ranged from 0 to 44 months (table 1).

There were no reported episodes of anaphylaxis and no difference in adverse effect frequency/severity seen between the home-treated and hospital-treated patients; at all centres, patients, both home and hospital, are reviewed 3–6 monthly and as part of this review are asked to report any adverse effects. For more serious adverse events, home-treated patients are advised to contact the prescribing centre immediately.

Home treatment had no negative impact on adherence, measured by prescription collection frequency/clinic attendance. In many cases, adherence was improved in the home-treated patients as they did not need to wait for hospital outpatient appointments or schedule these appointments to fit around home/work commitments. As a result of this, there was no difference in efficacy seen between patients treated in hospital or at home; efficacy monitoring was measured using UAS7 and quality-of-life scoring.

Of the 137 patients treated at home, only 1 patient has transferred back to hospital administration. This was a clinical decision by the medical team due to anaphylaxis unrelated to omalizumab and the patient's asthma becoming difficult to control. Overall, patients report a preference for home treatment as it has a lower impact on their daily living and increased flexibility. No negative feedback has been received.

The processes used to follow up and supply medication to the patients varied between the centres. All centres used non-medical prescribers with two centres having nurse-led clinics and one having a pharmacist-led clinic; all had medical consultant support if needed for more complex patients. All used the hospital pharmacy to supply omalizumab, with one centre supplying via an outsourced pharmacy. All patients were followed up every 3–6 months, either via telephone review or outpatient appointment.

DISCUSSION

In addition to the previously described UK cohort, Ghazanfar and Thomsen have also reported on the successful home self-administration of omalizumab in 40 patients with CSU in Denmark.[1 2] There has

Table 1 Number of patients on home treatment and duration of home treatment per centre

Centre	Leeds	Belfast	Cardiff
Total no of home treatment patients	101	20	16
Duration of home treatment (months)	0–44	0–10	0–26
Date home treatment started	November 2014	September 2017	May 2016

been one published report of home omalizumab treatment in patients with asthma.[3] No negative impact on patients treated at home over those treated in hospital was reported in either of these reviews.

Within the literature, the incidence of omalizumab anaphylaxis is reported to be 0.1%–0.2%.[4 5] Lieberman reviewed 96 cases of omalizumab anaphylaxis, 80% of which were in patients treated for asthma.[6] They reported that 69% of anaphylaxis occurred within the first two doses and 72% within the first three. In addition, 64% of cases occurred within the first 60 min (median 60 min) and 43% patients had prior anaphylaxis unrelated to omalizumab. Within our cohort, two of the three centres administer a minimum of three omalizumab injections within the hospital before transferring to home administration and in one centre they have a minimum of two doses. Initially, all three centres supplied home omalizumab patients with epinephrine autoinjectors in case of anaphylaxis. However, since the change in licensing, all three centres have reviewed practice and no longer routinely supply epinephrine autoinjectors.

With patients often requiring repeated courses of omalizumab for CSU, many centres are now individualising patient's treatment by extending or decreasing the interval between doses. This allows for the patient to be on the minimum dose that controls their symptoms and the ability to treat promptly if there is a significant increase in symptoms. Home treatment enables extension of interval without the administration delays that may be caused by waiting for an outpatient clinic appointment to be scheduled.

All supply is via the hospital pharmacy, with no centres using the homecare route. Currently, due to the recent license change, there is no established homecare service, but one of the centres is in the process of setting up a service. In line with national guidelines, patients with CSU require regular review and the follow-up period of 3–6 months allows for this. In one centre, due to the geographical area covered, the use of telephone reviews for the initial review offers advantages to both the patients and medical team in terms of clinic capacity.

The home treatment pathway is cost-effective as it reduces the number of hospital attendances and can provide further cost savings in the UK if supplied via outsourced pharmacies (or possibly in the future homecare delivery). Nursing clinic capacity is significantly improved; based on 15 min per patient (excluding observation time) per 6-month course, a total of 90 min per patient is saved. For this cohort of 137 patients, this is >25 working days per 6 months.

In conclusion, all three centres had similar outcomes in regards to home treatment with omalizumab for CSU. Home treatment is safe and effective and results in improved nursing clinic capacity, individualisation of treatment and has a lower impact on patient's daily living. It can lead to better adherence in some patients and is cost-effective when compared with hospital administration.

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