Paediatric severe asthma biologics service: from hospital to home

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ABSTRACT

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Children with severe asthma may be treated with biologic agents normally requiring 2-4 weekly injections in hospital. In March 2020, due to COVID-19, we needed to minimise hospital visits. We assessed whether biologics could be given safely at home. The multidisciplinary team identified children to be considered for home administration. This was virtually observed using a video link, and home spirometry was also performed. Feedback was obtained from carers and young people. Of 23 patients receiving biologics, 16 (70%) families agreed to homecare administration, 14 administered by parents/patients and 2 by a local nursing team. Video calls for omalizumab were observed on 56 occasions, mepolizumab on 19 occasions over 4 months (April–July). Medication was administered inaccurately on 2/75 occasions without any adverse events. Virtually observed home biologic administration in severe asthmatic children, supported by video calls and home spirometry, is feasible, safe and is positively perceived by children and their families

INTRODUCTION

Biologic agents such as omalizumab (Xolair) and mepolizumab (Nucala) administered subcutaneously are licensed therapies for children ≥ 6 years with severe asthma. However, as hypersensitivity reactions may occur¹ particularly on initiation of therapy and to ensure adherence to therapy, treatment is usually administered in hospital with careful monitoring of efficacy. On 16 March 2020 due to the COVID-19 pandemic, a hospital-wide lockdown was implemented, and most clinic consultations were carried out remotely. Thus, there was an urgent need to identify a new way of administering biologics to children, all of whom had previously been attending the Royal Brompton Hospital for their injections. In addition, families were concerned about the risk of cross-infection and were shielding so were unwilling to come to hospital. Omalizumab available as a pre-filled syringe and mepolizumab as an autoinjector are licensed for home use; however, safety data on home administration in this population are lacking. We hypothesised that many children with asthma could safely receive these agents at home supported by video calls and home spirometry without compromising asthma control.

METHODS

Children were identified as being suitable for home biologic administration if they had previously received at least three doses safely with no

What is already known?

 Biologic agents for asthma in children (omalizumab and mepolizumab) are traditionally administered in hospital 2–4 weekly to ensure adherence, tolerability and efficacy.

What this study adds?

Due to COVID-19, service reconfiguration occurred to reduce travel to hospital. We report on video-observed safe administration of biologics at home in children with asthma, including measuring spirometry and quality of life.

reactions, were prescribed a dose which could be given at home (mepolizumab 40 mg is not licensed for home use and is only available in vials), were deemed as suitable by the multidisciplinary team and the parents accepted to take on the role of administration supervised by video calls. It was challenging to find a provider to accept the contract for the approximately 500 adults and 30 children attending Royal Brompton. The chosen provider allowed flexibility of delivery to either the family or the local community nursing team. Our first patient was trained on 20 March 2020, and the rest by mid-April.

Training involved one face-to-face session with the patient and carer in hospital when injections were demonstrated and supervised, and the consent and registration forms for homecare were completed. This session lasted between 1 and 2 hours and was taken at the pace of the family. All subsequent injections were virtually observed and supervised via video call with the clinical nurse specialist (CNS) taking between 20 and 60 min depending on the clinical need at the time of the injection.

Parents/carers were provided with a spirometer (NuvoAir US, Boston, USA) to monitor forced expiratory volume in one second (FEV₁) and forcedvital capacity (FVC) at home. Initial set-up was conducted by the respiratory physiology team. Follow-up spirometry was performed by the parents supported by the CNS team.

Where there were concerns about adherence to inhaled corticosteroids, particularly those previously having directly observed therapy at school,



	Children on homecare—independent administration by parent/child		Children on homecare—administration by community nursing teams		Hospital administration	
Age range (years)	Omalizumab PFS	Mepolizumab autoinjector	Omalizumab PFS	Mepolizumab autoinjector	Omalizumab PFS	Mepolizumab autoinjector/vial
6–11	2	0	1	0	2	1 vial
2–18	7	5	1	0	1	3

PFS, pre-filled syringe

an electronic monitoring device (Smartinhaler; Nexus, New Zealand) was also issued.

Monthly monitoring was carried out by the CNS at the time of the injection which included spirometry, Asthma Control Test (ACT) or Children's Asthma Control Test (cACT), mini Paediatric Asthma Quality of Life Questionnaire (mPAQLQ), oral corticosteroid (OCS) requirement, unscheduled healthcare visits and general well-being in the preceding 4 weeks. We compared these measures of clinical control at the start of home administration with results after 3 months of home administration using Wilcoxon signed-rank test.

Regular 3 monthly clinic appointments with consultants continued virtually.

This was a service delivery evaluation and registered with the Royal Brompton Hospital audit department.

RESULTS

Sixteen of 23 patients (70%) median age 14.5 years (6-18 years), 9 males, fulfilled the criteria for homecare and accepted to take part. Fourteen parents/adolescents were suitable for independent administration, supported by video calls; two were suitable for administration by a local community CNS, also monitored by video link. Two patients aged 16-17 years administered their own injections. Table 1 shows patient details.

Seven patients were unsuitable for homecare administration (the dose not being licensed for home administration, n=1; the parent not wanting to administer at home, n=2; safeguarding concerns, n=2; previous mild reaction, n=1; and three doses not yet given, n=1). These patients continued to attend the Royal Brompton Hospital for biologic administration, monitoring and review.

Video calls for omalizumab were observed on 56 occasions, mepolizumab on 19 occasions over 4 months (April-July). Medication was administered inaccurately on 2/75 occasions (the plunger not fully activated, resulting in only a part of the dose administered, and in one case a syringe broke). Video supervision ensured that these issues were addressed in real time and appropriate action taken with families able to continue with home administration. There were no adverse consequences to the child.

Home spirometry represented another milestone in our service and was effective in providing accurate lung function data prior to the virtual appointments.

The feedback from families was positive (see below). Parents commented that they have found the support from the CNS, particularly the video call at the time of the injection, made them feel more confident and reduced their anxiety around administering injections; they found the training for the injections and home monitoring very useful, were appreciative of how fast the service had adapted and felt the homecare delivery service worked well. The children and young people have also highlighted a number of positives: they were reassured that they were being closely

monitored, relieved that they did not have to travel to the hospital and found the home monitoring devices easy to use.

FEV,, unscheduled healthcare visits and oral steroid use did not deteriorate with home administration; however, ACT and PAQLQ improved significantly over the first 3 months of home administration (table 2).

DISCUSSION

In this short report, we have shown that home administration of omalizumab and mepolizumab with virtual directly observed monitoring is feasible and acceptable to families. To our knowledge, we were the first paediatric service in the UK to implement homecare for biologic administration for children with severe asthma, supported by video calls and home monitoring including spirometry. The limited safety data (FEV₁, ACT, PAQLQ, unscheduled health visits and oral steroid usage) showed either no change or improvement, giving some reassurance that home administration did not compromise quality of care, although larger numbers of patients, longer duration and comparisons with the effects of lockdown in patients not receiving biologics are needed to confirm safety.

Video supervision serves two functions: assurance of safety and quality and support for the families; and assurance of adherence. The use of video monitoring to ensure the latter has been described before for inhaled therapy, and in other contexts such as tuberculosis and dementia.² This is important since one of the indications for biologics is refractory difficult asthma due to persistent poor adherence,³ and therapy in hospital means this is not an issue. It was therefore necessary to ensure that this advantage was not lost by home administration.

Future work will determine whether the administration of only the first dose in hospital is sufficient and roll this out to

Table 2Asthma control parameters in children on homeadministration of biologics							
	Pre-COVID-19	Post-COVID-19	Significance				
FEV ₁ % predicted (median, IQR)	89% (77%–95%) (n=14)	89% (82%–102%) (4-month data n=10, 3-month data n=14)	ns				
ACT (median, IQR)	18 (13–22) (n=14)	23 (19–24) (4-month data n=13, 3-month data n=14)	p=0.0005				
PAQLQ (median, range)	6.4 (4.6–6.8) (2-month data n=13, 1-month data n=14)	6.6 (6.3–6.8) (4-month data n=13, 3-month data n=14)	p=0.003				
OCS (median n=14)	0	0	-				
GP/A&E visit (median n=14)	0	0	-				
Hospital admission (median n=14)	0	0	-				

ACT. Asthma Control Test: A&E, accident and emergency: FEV., forced expiratory volume in one second ; GP, general practice; IQR, Inter quartile range; ns, not significant; OCS, oral corticosteroids; PAQLQ, Paediatric Asthma Quality of Life Questionnaire.

Box 1 Feedback from a parent and a child

Feedback from a parent:

'I was very nervous the first time, which is probably why I broke one syringe and locked myself out of two sharps bin. I was scared I might hurt my child, however, we managed well enough and now I feel fine doing them. It's definitely nice to be able to do the injections via a link with the Brompton which works well and I feel completely supported. The deliveries work well and so the whole process is stress free'.

Feedback from child (15 years):

At the start of the lockdown period, I found it difficult to adapt to the new routine and environment, however, over the course of months I was able to carry out my appointments at home. The hospital carried out the changes quickly and smoothly, which was very helpful as I did not have to worry too much about my wellbeing with the regular check-ups using video calls.

I found taking the injections from home not as fearful as other people may find, however, sometimes I fear that since a nurse is not physically there to guide you, you don't know what to do if something goes rather wrong. The video calls don't give you the full support but are still important in these situations.

On the other hand, taking medication from home saves a lot of time and I appreciate what the hospital was able to do to adapt to these changes and I'm still able to take my medication safely and communicate with a doctor or nurse on a regular basis. I did not experience any trouble in the delivery of medication which was delivered on time'.

all families by greater involvement of community paediatric nurses. However, it is clear that medical practice will change post-COVID, and we will not go back to 2019 practice.^{4 5} Here, we have demonstrated a new way of administration of biologics to children with asthma, which will be part of our routine practice going forward, and is within the scope of any difficult asthma centre. However, financial and time implications of this high-level service should be considered.

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