



Patients' views on subcutaneous IgG (SCIG) Home Therapy: results from The UK Subgam® Study.

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Abstract

Fifty patients with primary antibody deficiency (PAD) received weekly infusions of Subgam, an immunoglobulin G (IgG) recently licensed in the UK for subcutaneous (SC) use in adults and children. All patients had previously received intravenous (IV; n = 36) or SC (n = 14) IgG for at least 6 months. They were asked to complete a questionnaire rating comfort and convenience of their prior treatment. After 3 and 6 months on Subgam, they were asked to rate its comfort and convenience, how they felt their symptoms had been and how they liked Subgam overall compared with their previous treatment. For analysis, patients were separated according to the route of previous treatment and age (adult, teenager or child). Results at 6 months are summarised below: Ratings of convenience as 'very' plus 'quite' convenient were for: adults 93% for Subgam and 60% for prior IgG; teenagers 80% versus 40%; children 100% vs 42%. Comfort ratings of 'extremely' plus 'very' comfortable were for adults the same for both treatments (48%); teenagers 80% for Subgam vs 60% for prior IgG; children 58% vs 28%. Symptoms were regarded as being 'much better' plus 'better' in 52% of adults, 58% of teenagers and 66% of children. Only 2 patients regarded symptoms as being worse and one of these continued with Subgam long-term. Overall preferences for Subgam were 'much more' plus 'more' for 72% of adults, 100% of teenagers and 80% of children. In conclusion, Subgam is suitable for Home Therapy and the regimen is popular with patients of all ages. Subgam is an IgG which is now licensed for subcutaneous use in adults and children.

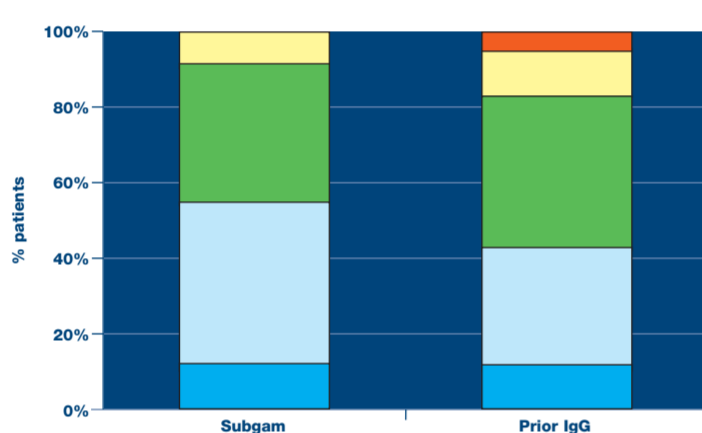
Introduction

IgG given intravenously (IV IgG) is the mainstream of treatment for PAD and has been shown to be effective in maintaining plasma IgG levels and reducing infections (1). A number of patients (or their carers) have been able to learn the technique of Subgam administration with a partner to enable them to move onto home therapy. Over the last decade, an IgG preparation for rapid subcutaneous (SC) infusion has been shown to be effective, well-tolerated and popular with many patients (2,3,4). Venous access can be difficult in some patients; particularly children, and they are unlikely to progress to home therapy with IV IgG (5). For those patients, subcutaneous (SC) IgG offers the only option for home therapy. As the SC IgG product can be infused using small portable syringe drivers, the patient has much more freedom of movement during the infusion. Furthermore, there is a low risk of systemic reactions with SC IgG (6), which makes it all the more suitable for home infusions.

Results

Figure 1: How comfortable patients found Subgam®, compared with their previous IgG (n=42)

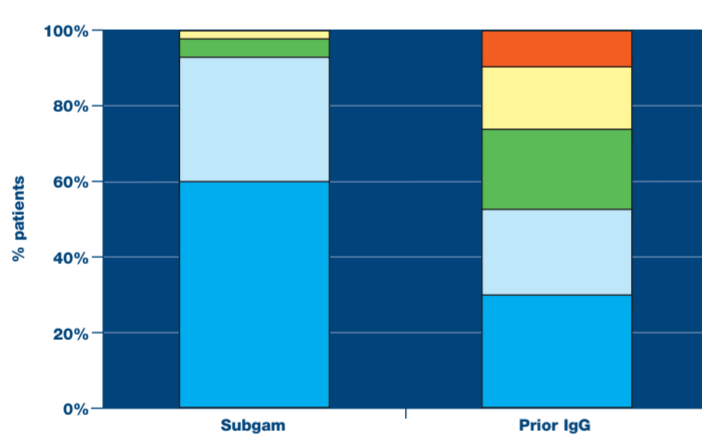
Key: Extremely uncomfortable Not very comfortable Quite comfortable Very comfortable Extremely comfortable



- Overall, 90% of patients found infusions with Subgam quite, very or extremely comfortable (55% found it very or extremely comfortable).
- No patients thought that Subgam infusions were extremely uncomfortable.
- Furthermore, 29% of patients gave Subgam a higher rating for comfort than they gave their prior IgG compared with only 19% who gave Subgam a lower rating.

Figure 3: How convenient patients found Subgam®, compared with their previous IgG (n=42)

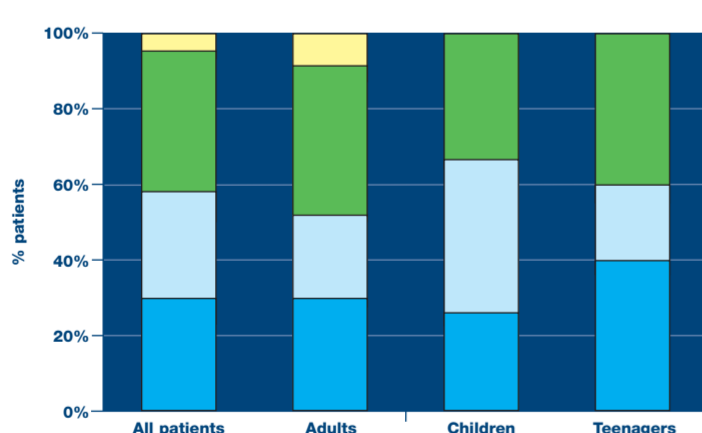
Key: Very inconvenient Quite inconvenient Neither convenient nor inconvenient Quite convenient Very convenient



- Overall, 93% patients found Subgam convenient (60% found it very convenient).
- No patients found Subgam 'very inconvenient' and only 1 found it 'quite inconvenient'.
- 52% patients gave Subgam a higher rating for convenience than they gave their prior IgG compared with only 3 patients (7%) who gave it a lower rating (all 3 patients were previously on SC IgG).

Figure 5: Symptoms on Subgam®, compared with previous IgG (all patients n=43, adults n=23, teenagers n=5 and children n=15)

Key: Much worse Worse Same Better Much better



- 58% patients felt that their symptoms were either 'better' or 'much better' than they were on previous therapy.
- Only 2 patients felt that their symptoms were 'worse'. However, one of them elected to continue in the trial after the end of the first study phase.

Summary and conclusions

The advent of home therapy programmes has given many patients a better quality of life as it is more convenient than receiving infusions at hospital and allows patients to have a greater feeling of control over their condition. However, a limited number of patients are suited to home therapy with IV IgG. Subgam is an IgG licensed for subcutaneous use in adults and children, and is suitable for home therapy even in children and other patients with poor venous access. Subgam has proved to be extremely popular with the patients in our study. In general, patients (particularly children) found Subgam more convenient than their previous IgG therapy. A significant number of patients felt that their symptoms had been better on Subgam than on their prior treatment, and overall 79% of patients preferred Subgam to their previous treatment.

References

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Subgam is a 16% isotonic solution of IgG at pH 6.5-6.7, with no added stabilisers or antimicrobial preservatives. At least 98% of protein present in the solution is IgG of which at least 90% is monomeric. The subclass distribution is IgG1 (64%), IgG2 (29%), IgG3 (6%) and IgG4 (1%). Because of its purity, there is little or no contamination with IgA, which in assays of many batches has been shown to be <0.01% of protein. The product is prepared from plasma collected from screened, healthy, volunteer donors in the USA. Besides the conventional serological tests on each donation, minipools of donations are tested for HIV, HAV, HBV, HCV and parvovirus B19 by NAT (PCR). If any donation fails any of these tests it is discarded. The manufacturing process includes steps which purify the IgG and are shown to be able to remove model viruses, as well as the well-established solvent/detergent step specifically aimed at the major human pathogenic viruses potentially transmissible by plasma-derived products.

Here we present patient opinions from The UK Subgam Study, set up by BPL in June 2000 to determine the long-term effects of Subgam by rapid subcutaneous infusion in a population of patients with primary antibody deficiency (PAD).

Methods

Study population

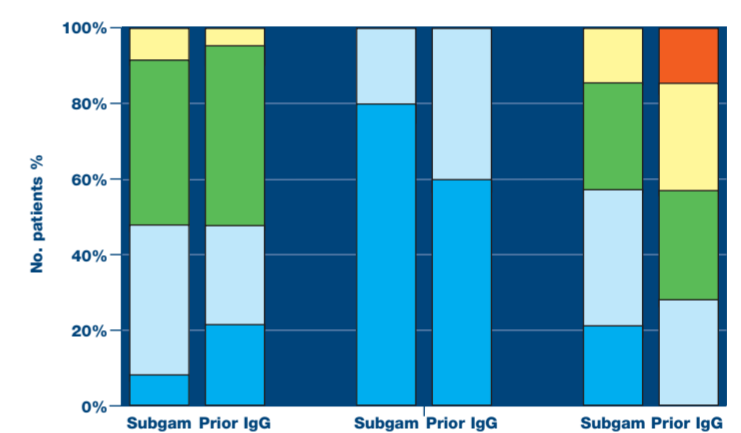
- Fifty patients with stable primary antibody deficiency (PAD)
- Receiving IVIG or SCIG for at least 6 months prior to study entry

Design

This assessment formed part of an open single arm study (described by Dash, Gooi and Johnson, this meeting). Patients received 3 infusions of their prior IgG before starting Subgam and were asked to complete a questionnaire rating comfort and convenience of that treatment. After 3 and 6 months of weekly subcutaneous infusions with Subgam, they (or in the case of young children, their carers) were asked to complete questionnaires to rate comfort and convenience of Subgam, how they felt their symptoms had been and how they liked Subgam overall compared with their previous treatment. For analysis, patients were separated according to age (adult >19 years, teenager = 12-19 years or child <12 years). Opinions recorded after 6 months on Subgam compared with those given on prior treatment are presented below.

Figure 2: How comfortable patients found Subgam®, compared with their previous IgG (adults n=23, teenagers n=5 & children n=14)

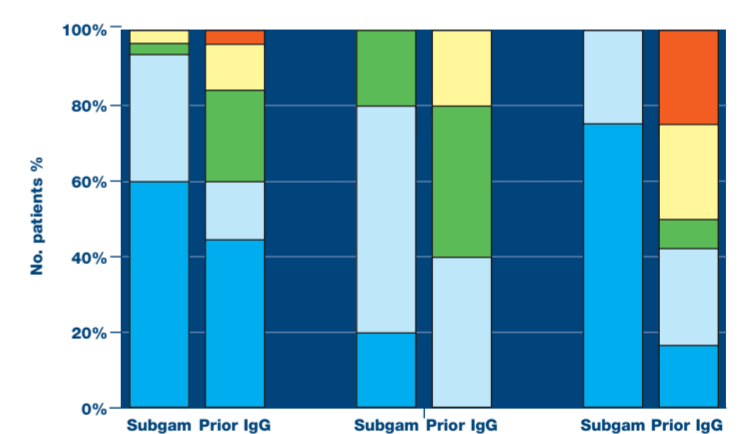
Key: Extremely uncomfortable Not very comfortable Quite comfortable Very comfortable Extremely comfortable



- 50% of children found Subgam more comfortable than their prior IgG.
- 100% teenagers found Subgam either 'extremely' or 'very' comfortable.

Figure 4: How convenient patients found Subgam®, compared with their previous IgG (adults n=23, teenagers n=5 & children n=14)

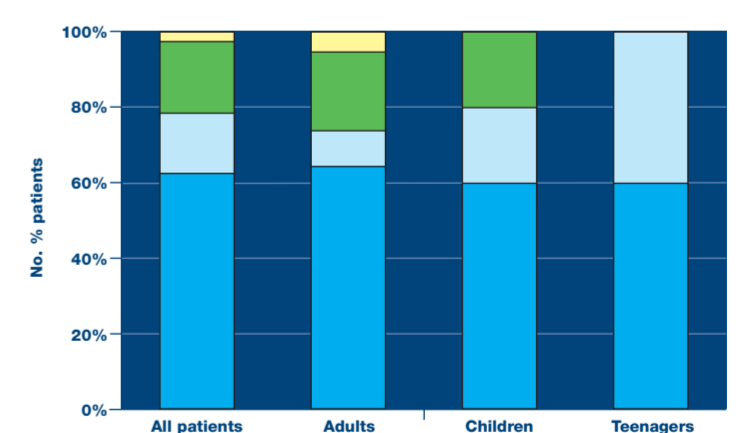
Key: Very inconvenient Quite inconvenient Neither convenient nor inconvenient Quite convenient Very convenient



- 100% children found Subgam either 'quite' or 'very' convenient.
- 64% of children gave Subgam a higher rating for convenience than their prior IgG.

Figure 6: How patients liked Subgam®, compared with previous IgG (all patients n=43, adults n=23, teenagers n=5 and children n=15)

Key: Not at all Not as much Same More Much more



- 79% patients preferred Subgam to their prior IgG.
- 63% patients liked Subgam 'much more' than their prior IgG.
- Only 3 adult patients previously on SC IgG did not like Subgam 'as much' as their prior IgG. However, 2 of them chose to continue with Subgam at the end of the 1st study phase.
- 100% of teenagers preferred Subgam to their prior IgG.

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