Subcutaneous immunoglobulin therapy at home

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In this article...

- The benefits of offering treatment at home
- How the programme was implemented
- The future direction for subcutaneous immunoglobulin therapy

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Abstract


Subcutaneous immunoglobulin (SCIg) replacement therapy is a new clinical service development in adult respiratory care undertaken at the Royal Brompton and Harefield Foundation Trust. SCIg therapy reduces appropriate patients’ susceptibility to recurrent acute and chronic respiratory infections. Patients with specific chronic respiratory conditions and antibody deficiency can be treated with SCIg therapy at home, rather than with intravenous immunoglobulin (IVIg) therapy in hospital. Using a personalised teaching programme and managing the daily demands of the clinical service promotes greater concordance with treatment. With over 34% of our immunoglobulin therapy patients now on SCIg replacement therapy, this treatment innovation has brought about high levels of patient satisfaction and cost savings to trust budgets.

5 key points

1. Immunoglobulins are antibodies prepared from plasma that help keep the body free from infection.

2. Before the introduction of antibiotics, patients diagnosed with antibody deficiency died prematurely from acute respiratory infections.

3. Subcutaneous immunoglobulin (SCIg) therapy reduces patients’ susceptibility to recurrent acute and chronic respiratory infections.

4. Managing their own treatment gives patients greater control over their condition and promotes concordance.

5. Delivering SCIg therapy at home saves the NHS money and is popular with patients.

Intravenous immunoglobulin therapy could be replaced by home-based SCIg therapy.
on patient survival rates (Pourpak et al, 2006). Today, developments in the manufacturing process mean that immunoglobulin replacement therapies are well tolerated, no matter which administrative route patients choose to receive.

From the time SCIG became available in the late 1990s, this administrative route has been compared with IVIG: clinical trials have shown it to be equivalent in terms of serum immunoglobulin concentrations achieved and in prevention against serious bacterial infections in patients with antibody deficiency (Chapel et al, 2000).

For some patients, a local injection site reaction occurs following administration of SCIG but this is usually short lived and well tolerated. SCIG treatment effectiveness has been shown to be comparable to IVIG treatment (Table 1), with respect to annual rates of serious bacterial infections such as pneumonia. However, patients receiving SCIG treatment have reported better quality-of-life outcomes in terms of reduced time spent admitted to hospital, on antibiotics and fewer days missed from work or school (Eades-Perner et al, 2007; Gardulf et al, 2006).

**Implementation of a home SCIG therapy programme**

Before starting the service I visited other immunology centres to understand how they deliver their SCIG service. The views of patients undergoing IVIG therapy were then sought to see whether they would consider switching their treatment delivery to a home therapy SCIG option. Having explored the feasibility and potential demand for this new service, a team consisting of a ward manager, nursing staff, administrator, pharmacist, procurement manager, directorate manager and consultant immunologist explored how to move the initiative forward.

Treatment guidelines were written and accepted by the trust’s drug and therapeutic committee, and standard operating procedures (SOPs) outlining the nursing responsibilities and the teaching programme were drawn up. The SOPs included:

- Management of adverse events;
- Letters of notifications to GPs; and
- Test papers for patients and infusion partners to complete to ensure they fully understood the treatment regimen.

Home-care contracts were then established and infusion equipment purchased. The role of home care is to deliver immunoglobulin and ancillaries to patients’ homes while removing any clinical waste material, for example, sharps bins.

Standard letters to primary care trusts were written, detailing the new home therapy option for patients. This would be a financially attractive package, saving an estimated £4,000–6,000 per patient per year. Further financial savings have been made from patients who required hospital transport but are now treated at home.

Patients are given a personalised teaching programme in hospital by the clinical nurse specialist on how to administer SCIG replacement therapy at home. This programme details knowing:

- How to store and draw up the product;
- When not to infuse;
- How to manage and report adverse events; and
- The importance of recording batch numbers.

The CNS’ additional nursing responsibilities lie in:

- Liaising with the pharmacy department to maintain prescriptions;
- Troubleshooting service concerns;
- Maintaining patient entries on the local and national databases; and
- Attending the trust’s immunoglobulin demand-management panel meetings.

Patients are welcome to call the CNS for advice, especially if they have an opportunistic respiratory infection and need antibiotic guidance. Also, if they have concerns about their treatment administration regimen once at home, they can call to discuss adapting their treatment approach.

Box 1 outlines key points in setting up a home SCIG service.

**SCIG service outcome**

The benefits of this project are that it places patients’ requirements first and patients are empowered to take charge of their treatment. Patients understand the treatment regimen is more intense, with weekly injections rather than infusions every three weeks, but managing their own treatment gives them greater control over their condition and promotes concordance with treatment. Some patients will bring their infusion log books to clinic to show the consultant immunologist how they are getting on with their treatment; for others, changes to their personal circumstances may mean the delivery of the treatment requires adjustment.

Patients can administer their SCIG every 7–10 days, making the treatment regimen more flexible and giving them the opportunity to infuse around a two-week holiday. This treatment regimen requires blood to be taken every three months to ensure immunoglobulin trough levels remain within therapeutic range. Other blood markers are also checked to ensure patients are well and free from viral infections. In some instances GP surgeries report their results to the service lead, which reduces a patient’s burden of attending regular hospital phlebotomy clinics. As this treatment is safe to administer at home, with minimal adverse events being reported, patients only need to be clinically reviewed once every six months – as long as their trough levels remain within an acceptable range and their underlying condition remains stable.

Our first SCIG service survey was conducted in May 2012 to explore patient satisfaction with the service option. A 61% (18 patients) postal response rate was achieved, the average age of participants was 47 years and there was an equal gender ratio. Our

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**FIG 1. INFECTION AND INFLAMMATION CYCLE**

- **Microbial infection** For example, haemophilus influenza, Pseudomonas aeruginosa
- **Inflammation** Neutrophilic inflammation causes damage to the tissue through proteolytic enzymes and oxidative stress
- **Tissue damage** To epithelial cells and the structure of the airway wall leading to increased mucus production, which is poorly cleared
- **Impaired lung defences** For example, antibody deficiency, primary ciliary dyskinesia, cystic fibrosis
service users came from Ireland and counties in the west and south-west of England. Our main findings were that 94% strongly agreed that they preferred the SCIG replacement therapy option to IVig treatment and that 89% would strongly recommend SCIG therapy to other patients considering it. One patient’s response stated that: “SCIg therapy allowed me more freedom: I can choose the time and place that I want to administer the treatment rather than spending all day at the hospital every three weeks. I also used hospital transport and waited several hours to get home.”

When asked whether there were any downsides to receiving SCIG therapy, 72% of responders reported there were none but others remarked on infusion frequency, pain associated with needle insertion and lack of sleep on the day of treatment.

Conclusion
The future direction of SCIG replacement therapy is exciting; newer ways of delivering it have been explored, such as a rapid-push technique, which takes less time. Hyalurondase-facilitated administration assists with immunoglobulin uptake to overcome large volumes being administered at a single site and is suitable for patients who receive large weekly infusion volumes (Misbah et al, 2009). In addition, a new concentrated product has been manufactured to reduce the weekly volume requirement and, combined with the rapid-push technique, has the potential to reduce the weekly treatment burden to every second week.

Studies into IVig show increased doses reduce lung-function decline and exacerbation frequency in patients with immune deficiencies and chronic comorbidities (Chen et al, 2011; Orange et al, 2011; Lucas et al, 2010). The introduction of SCIG replacement therapy at the Royal Brompton and Heartfield Foundation Trust has given respiratory patients with antibody deficiencies choice over their treatment delivery options. This therapy option constitutes a cost-saving opportunity to the NHS and has resulted in a high level of treatment satisfaction to our patient population.

References

Table 1: Comparison of Intravenous and Subcutaneous Immunoglobulin Therapies

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<thead>
<tr>
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<th>Intravenous Immunoglobulin (IVIg) Therapy</th>
<th>Subcutaneous Immunoglobulin (SCIG) Therapy</th>
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<tbody>
<tr>
<td>Pharmacokinetics</td>
<td>Wide difference in immunoglobulin levels between peak and trough measurements</td>
<td>More consistent serum immunoglobulin levels</td>
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<td>Efficacy</td>
<td>Long-established clinical practice has demonstrated treatment efficacy</td>
<td>Two prospective trials demonstrate non-inferiority to IVIg</td>
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<td>Side-effects</td>
<td>Infrequent – headaches, rash, shivers and muscle ache</td>
<td>Uncommon – usually infusion site reaction only</td>
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<td>Patient satisfaction</td>
<td>Offers patients a better option when experiencing difficulty with needle insertion/self-injection. Viewed as a preferable approach for patients who have difficulty with compliance</td>
<td>Offers flexibility to infusion regimen. Number of studies have reported enhanced quality of life in patients with immune deficiency</td>
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Box 1: Key Points for Setting up an SCIG Service

- **Reduce duplication of effort** by contacting similar existing services to discuss what is involved, the implications, and whether others would be willing to share any documentation, such as guidelines or protocols. Existing services can provide advice on appropriate infusion pumps, tips on how to run the service innovation when working with a home delivery company and how to troubleshoot problems.
- **Good communication** is vital for the service to succeed. One early hurdle faced was the time delay in getting the go-ahead from the primary care trust once the patient had expressed interest in starting SCIG therapy. Good communication should be established between the procurement department, the lead nurse and the PCT.
- **Predicting service demand** is essential to meet patients’ ongoing needs. Our initial estimate of those wishing to start home SCIG replacement therapy was 20% of our IVIg patients – after four years on this programme, 34% of our patients now infuse at home.
- **Working closely with patients** is key to the success of the service. Approximately 15% of patients during their learning period unknowingly had “needle phobia” when it came to self-inserting needles. Weekly teaching sessions over the learning period gave patients the opportunity to overcome their concerns; towards the end of their learning period, these patients successfully insert needles independently.
- **Keep everyone involved and well informed**. Once patients are signed off as competent to administer their home therapy, GPs are informed by letter. Patients also receive a letter stating they can deliver this treatment at home; this letter is useful for patients in acute situations to notify local hospitals of their ongoing therapy need. A clinical nurse specialist provides letters for airport authorities to enable patients to travel with the necessary drug and ancillaries.