



Home-based subcutaneous immunoglobulin therapy vs hospital-based intravenous immunoglobulin therapy: A prospective economic analysis



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ABSTRACT

Background: Home-based subcutaneous immunoglobulin (SCIg) administration used for immunoglobulin replacement therapy for patients with primary immunodeficiency has been demonstrated to have benefits compared with hospital-based intravenous immunoglobulin (IVIg) therapy.

Objective: To estimate the cost savings associated with treating eligible patients with primary immunodeficiency with home-based SCiG compared with hospital-based IViG in a prospective study.

Methods: This study was a 12-month prospective observational study that collected information from patient charts, directly from the nurse for time spent with patients and materials used, and directly from the physicians for billing. Data were collected on case report forms at each follow-up. Data were entered in a web-based REDCap database and statistical comparisons were performed.

Results: The average hospital (including hospital personnel such as nurses) and physician costs were significantly lower in the SCiG group (\$1,836 and \$84, respectively) than in the IViG group (\$4,187 and \$744, respectively), which supported the findings in the number of hospital and physician visits in each group. The total cost was reported from the hospital's (only hospital-related costs) and the health system's (hospital- and physician-related costs) perspectives. For the 2 perspectives, the SCiG group reported significantly lower average total costs than the IViG group.

Conclusion: This is the first prospective analysis of the cost savings associated with home-based SCiG therapy compared with hospital-based IViG therapy. These findings could help justify provision of home-based therapy training to suitable patients to lower health care costs or improve the capacity of care.

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Introduction

Patients with primary immunodeficiency are predisposed to acute, recurrent, and chronic infections.¹ These patients who cannot produce their own antibodies are treated passively with immunoglobulin derived from plasma donors to decrease the frequency and severity of infections.² In Canada, the total cost of intravenous immunoglobulin (IVIg) for 2005 to 2006 was \$196 million and has increased over time.¹ Subcutaneous immunoglobulin (SCiG) is widely

used in Europe and the United States.³ SCiG is becoming more commonly used in Canada since being licensed in 2011. Unlike IViG, in Canada SCiG has advantages because it can be administered at home; thus, it could have cost savings while improving patients' quality of life.⁴

A Canadian economic evaluation, conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH), comparing home-based SCiG with hospital-based IViG found that switching from hospital-based IViG to SCiG could save \$700 to \$1,000 per patient per year.¹ However, the investigators recommended SCiG as an alternative only for patients with contraindications to IViG and poor venous access because the analysis was based on limited data.¹ Studies have found that SCiG is comparable to IViG for rate of infections and hospitalizations.^{5–8} Two systematic reviews of economic evidence comparing SCiG and IViG therapies found 10 published studies in total.^{9,10} All 10 studies found that home-based SCiG was less costly than hospital-based IViG.^{9,10} In addition, 8 studies (3 Canadian studies, 2 French studies, 1 German study, 1 British study, and 1 Swedish study) looked at the costs of the 2 treatments from

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the public health care payer perspective, and 2 studies (1 was conducted in France and the other was conducted in Sweden) looked at the costs of the treatments from the hospital's perspective. More recently, 1 Swiss study showed a significant cost decrease in switching a patient from IVIg to SCIg.¹¹ Overall, the findings showed that home-based SCIg was less costly than IVIg; however, most studies estimated the economic impact using expert opinion or secondary data from the literature.^{9–12}

The Canadian economic evaluation was released in early 2008,¹ yet the uptake of SCIg in Ontario has remained low. Several factors might explain the low uptake: (1) the recommendation from the CADTH report was based on limited clinical and economic evidence and (2) cost-effectiveness analysis might not be the most appropriate tool for informing resource allocation decisions at a hospital level. Hence, the present study aimed to add another piece of economic evidence to address the needs of hospital administrators and public health care payers.

Methods

Study Population and Setting

Written consent was obtained from participants. Institutional review board (St Michael's Hospital, Toronto, Ontario, Canada) review and approval was obtained. We conducted a prospective cohort study at 1 adult primary immunodeficiency clinic in Toronto over a 12-month period to compare costs associated with hospital-based IVIg with those associated with home-based SCIg. There were 2 cohorts in this study: (1) the IVIg cohort included existing and new patients who received hospital-based IVIg and (2) the SCIg cohort included existing and new patients who received home-based SCIg. Eligible patients were at least 18 years old with a confirmed diagnosis of common variable immunodeficiency or X-linked agammaglobulinemia and no contraindications to immunoglobulin treatment.

Interventions

Patients were treated with IVIg or SCIg in accordance with the current standard of care. Because there were sometimes clinical reasons to select one treatment modality over another (eg, poor venous access, history of systemic adverse reactions), the decision was left to the discretion of the treating clinician(s). Patient preference also could have played a role. Ethical approval was obtained to approach patients for enrollment in the study sequentially until local recruitment targets were met for each arm and then enrollment was closed. The 2 treatment cohorts were followed for a 12-month period.

Cost

Costs included those associated with physician visits (fee codes a133, a134, a135, a138, and g389) and hospital costs over a 12-month period. The cost for each physician visit with a specified fee code was obtained from the Ontario Schedule of Benefits for Physician Services under the Health Insurance Act (version December 21, 2015).¹³ Hospital costs, obtained from the Decision Support Services Department at St Michael's Hospital, were separated into 2 categories (ie, variable and fixed), and 4 subcategories (ie, ambulatory care services, clinical laboratory, medical imaging, and allied health) within each category. The hospital costs captured all relevant costs to the hospital including costs of all hospital personnel (such as nurses and technicians) involved in the specified visits. Costs were reported in 2015 dollars.

Other Variables

In addition to costs, we reported baseline characteristics, namely age (in years), sex, weight (kilograms), and comorbidities (which included autoimmune liver disease, bronchiectasis, celiac disease, cytopenia, inflammatory bowel disease, lymphadenopathy, organomegaly, otitis, pneumonia, rheumatoid arthritis and systemic lupus erythematosus, sinusitis, and others). We also examined the number of physician visits, hospital visits, and nursing time during the 12-month period.

Analysis

Descriptive analyses were performed to describe the study cohort overall and by groups using *t* test for continuous variables and χ^2 test for categorical variables.

We conducted the analysis from 2 perspectives: (1) the hospital's perspective, which included costs to the hospital (eg, nursing time, overhead, general supplies, and patient-specific supplies)¹⁴ but did not include physician fees or outpatient prescription drug costs, and (2) the health system's perspective, which included physician fees in addition to hospital costs. The time horizon of the analysis was 1 year.

The generalized linear model with log link and Poisson family was used to estimate the difference in expected costs between the 2 groups adjusted for age, sex, weight, and whether the patient had at least 1 current comorbidity. The total cost was the dependent variable. The intervention variable (SCIg or IVIg) was the primary independent variable. To arrive at the chosen model, the modified park test, including the Pearson correlation test and Pregibon link test, was used to identify the most appropriate family distribution.¹⁵

Results

The analysis included 30 patients in the IVIg group and 27 patients in the SCIg group. The average age and baseline weight were not significantly different between the 2 groups. Specifically, the mean age was 43.7 ± 15.6 years for the IVIg group and 42.0 ± 14.7 years for the SCIg group. The mean weight was 69.9 ± 12.6 kg for the IVIg group and 75.1 ± 10.5 kg for the SCIg group. Weights were not available for 5 patients. In addition, the proportion of male patients in the 2 groups was similar (43% for the IVIg group and 52% for the SCIg group). However, the number of patients with at least 1 comorbidity at baseline was significantly larger in the IVIg group than in the SCIg group ($P = .0022$ with Bonferroni adjustment). **Table 1** present the baseline characteristics of the study population from descriptive analyses.

Typical patients on IVIg therapy came to the hospital, where they had an intravenous line inserted by a nurse before the initiation of immunoglobulin infusion. Once the infusion began, the average time of infusion was variable but generally was approximately 2 to 3 hours. The duration of the infusion depended on tolerability of the product and underlying comorbidities. Although there was no study-mandated visit schedule, it was anticipated that patients in the IVIg cohort would visit the clinic every 3 to 4 weeks to receive their treatment in accordance with usual care.

For patients on SCIg therapy, initiation of SCIg therapy required training by a qualified nurse. In general, this training occurred on a 1-on-1 basis at 1 visit. Once the patients had been trained, they infused the product on their own at home. The frequency of those infusions varied depending on patient preference provided the patients at least administered the calculated weekly dosage within the week. In general, patients in this setting preferred to inject small volumes repeatedly throughout the week, ranging from 1 to 7 times a week. For patients transitioning from IVIg to SCIg at the beginning of the study, the SCIg treatment was initiated at a dose

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