

Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home

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Background: A large number of children and adults with primary antibody deficiencies need lifelong IgG replacement therapy. It is mostly unknown what effect the choice of replacement therapy has on the patients' health-related quality of life (HRQOL) and treatment satisfaction (TS).

Objective: To investigate whether a switch from hospital-based intravenous IgG (IVIG) to home-based subcutaneous IgG (SCIG) therapy would improve the HRQOL and TS.

Methods: Fifteen children (<14 years; hospital-based IVIG therapy at enrollment) and 32 adults (≥14 years; 22 on hospital-based IVIG and 10 on home-based SCIG therapy at enrollment) were included. Questionnaires were completed at

baseline and at 6 and 10 months: the Child Health Questionnaire-Parental Form 50 (children) or Short Form 36 (adults), the Life Quality Index, and questions regarding therapy preferences.

Results: The SCIG home therapy was reported to give better health ($P = .001$) and improved school/social functioning ($P = .02$) for the children, reduced emotional distress ($P = .02$) and limitations on personal time for the parents ($P = .004$), and fewer limitations on family activities ($P = .002$). Adults switching therapy reported improved vitality ($P = .04$), mental health ($P = .05$), and social functioning ($P = .01$). Adults already on SCIG home therapy at enrollment retained high HRQOL and TS scores. The SCIG home therapy improved TS because it led to greater independence and better therapy convenience ($P < .05$). The patients preferred the SCIG administration route and having the treatment at home.

Conclusions: Home-based SCIG therapy improves several important aspects of HRQOL and provides the patients with primary antibody deficiencies and their families with greater independence and better control of the therapy situation and daily life. SCIG home therapy is an appreciated therapeutic alternative for adults and children in need of lifelong IgG replacement therapy. (*J Allergy Clin Immunol* 2004;114:936-42.)

Key words: Primary immunodeficiencies, subcutaneous IgG therapy, intravenous IgG therapy, quality of life, home care, patient satisfaction, self-care, nursing

Primary immunodeficiency diseases result from inborn defects of the immune system. Most of these diseases include a defective antibody formation (primary antibody deficiency [PAD]), which leads to increased susceptibility to bacterial infections of the mucous membranes, notably of the sinopulmonary tract.¹ Many children and adults with PAD need lifelong replacement therapy with IgG. Rapid subcutaneous IgG (SCIG) infusions have been shown to be easy to learn for both adult patients^{2,3} and children/parents^{4,5} and to be safe, with no or few systemic adverse reactions²⁻¹⁰ and with no transmission of the hepatitis C virus.³ It results in normalized serum

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Abbreviations used

CHQ-PF50: Child Health Questionnaire–Parental Form 50
HRQOL: Health-related quality of life
IVIG: Intravenous IgG
LQI: Life Quality Index
PAD: Primary antibody deficiency
SCIG: Subcutaneous IgG
SF-36: Short Form 36
TS: Treatment satisfaction

IgG concentrations^{2-6,10} corresponding to those seen in intravenous IgG (IVIG) replacement therapy and with as few infections as during IVIG therapy.⁷

Data regarding self-reported outcomes in the health-related quality of life (HRQOL) due to PAD and its replacement therapy are rare in adults¹¹ and lacking in children and their families. The aims of the study were therefore to describe self-reported HRQOL and treatment satisfaction (TS) in children and adults with PAD and to investigate whether the introduction of SCIG replacement therapy as self-infusions at home would improve the HRQOL and TS.

METHODS

Patients

The inclusion criteria were a diagnosis of PAD according to definition,¹ age between 2 and 75 years, IVIG or SCIG replacement therapy for at least 6 months, stable serum IgG trough levels (≥ 5 g/L) before enrollment, no other major chronic diseases, and an ability and willingness to answer questionnaires. Sixty eligible patients at 12 study sites in 6 countries were invited, and 58 agreed to participate. The participants were divided into 2 groups—those younger than 14 years (referred to as children; $n = 17$ at enrollment) and those 14 years or older (adults; $n = 41$)—according to recommendations from the authors of the 2 generic HRQOL questionnaires used for the study.^{12,13} Medical data regarding the participants are shown in Table I. Thirty-seven patients received hospital-based IVIG at enrollment, and 10 patients already used SCIG self-infusions at home. The main reason for including patients already receiving SCIG was that these patients, who had a long experience with self-administered SCIG therapy at home, served as controls to gauge the study-specific effects. The mean IgG trough level directly before the study start was 7.9 g/L (range, 5.5–11.9 g/L) for the children. For the adults, the corresponding figures were 8.3 g/L (range, 5.9–15.8 g/L) for those on IVIG therapy at enrollment and 9.0 g/L (range, 6.6–14.2 g/L) for those on SCIG therapy at enrollment.

The participants answered the questionnaires thrice: at baseline and after 6 and 10 months. Not all the participants filled in all the questionnaires. However, in no case was the failure to complete the questionnaires attributed to the health of the participants (Table I).

SCIG therapy

The IgG was given as weekly infusions by using a technique described previously.^{2-7,9,10} Each participant completed 43 infusions (10 months) with a liquid pasteurized polyvalent human 16% (160 mg/mL) IgG preparation intended for subcutaneous use (ZLB Behring GmbH, Marburg, Germany [formerly Aventis Behring GmbH, Marburg, Germany]). The patients continued with a dosage equivalent to the dosage during the previous IgG replacement therapy. Weekly dosages ranged between 50 and 150 mg/kg body weight.

TABLE I. Demographic and medical patient data

Variable	Children (<14 y)	Adults (≥ 14 y)
No. patients enrolled	17	41
No. evaluable patients	15*†	32†‡§
Sex (male/female)	15/0	20/12
Age (y)		
Median	7	33.5
Range	3–13	14–74
Diagnosis (No. patients)		
CVID	3	25
IgG subclass deficiency	2	0
Other hypo- or gamma globulinemia	10	7
IgG therapy at enrollment (No. patients)		
Intravenous IgG	15	22
Subcutaneous IgG	0	10
Serum IgG trough levels	7.9	8.3
before study, mean (range)	(5.5–11.9)	(5.9–15.8)
		9.0 (6.6–14.2)¶

CVID, Common variable immunodeficiency.

*Two children were excluded from the final evaluation because of belated assessments (baseline, $n = 1$; 6 months, $n = 1$).

†Study sites and number of patients evaluated: Brazil, children $n = 0$ /adults $n = 3$; Germany, $n = 6$ / $n = 13$; Poland, $n = 9$ / $n = 4$; Spain, $n = 0$ / $n = 2$; Sweden, $n = 0$ / $n = 10$.

‡Five adults were excluded from final evaluation because of belated assessments (baseline, $n = 1$; 6 months, $n = 2$; 10 months, $n = 2$).

§Three adults prematurely discontinued the study before the 6-month assessment (1 protocol violation [ie, a patient with renal failure was wrongly included], 1 suspected systemic adverse reaction in a patient with a history of such reactions during IVIG infusions, and, in 1 case, missed follow-ups because of a long stay abroad).

||One adult did not complete the questionnaires at the 10-month assessment.

¶Adults on subcutaneous IgG therapy at enrollment.

Home therapy

All participants were trained and supervised once per week at the local hospital for 4 to 6 training sessions and had to show practical skill, knowledge, and confidence in the SCIG administration route before being transferred to self-infusions at home. The parents gave the infusions to their children or supervised the treatment. The participants visited their clinic every fourth week for medical and nursing follow-ups and to verify that the infusion technique was correct.

Questionnaires: HRQOL

The Child Health Questionnaire–Parental Form 50 (CHQ-PF50)¹² was used for the children and answered by the parents. It focuses on the physical and psychosocial functioning and well-being of the child and his or her family and aggregates to 15 concepts in total (Table II). For this study, the 1 stand-alone global item “change in health” was not used because it has a 1-year recall period. Higher scores indicate a better HRQOL.

Short Form 36 (SF-36) was used for the adults. It consists of 35 items forming 8 subscales: physical function (10 items), role-physical (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social function (2 items), role-emotional (3 items), and mental health (5 items).^{13,14} As in the CHQ-PF50, the 1-year comparison of health was excluded. Higher scores indicate a better HRQOL.

TABLE II. Concepts measured in the CHQ-PF50

Concept	Abbreviation	No. items	Definition
Physical functioning	PF	6	Limitations in physical activities
Role/social-emotional, behavioral	REB	3	Limitations in school, work, or social activities because of emotional or behavioral problems
Role/social-physical	RP	2	Limitations in school, work, or social activities because of physical problems
Bodily pain	BP	2	Intensity/frequency of pain/discomfort
Behavior	BE	6*	Ability to get along with others, behavioral problems including aggression, delinquency, impulsivity, and social withdrawal
Mental health	MH	5	Positive and negative states including anxiety, depression, and positive affect
Self-esteem	SE	6	Satisfaction with school, athletic ability, appearance, ability to get along with others
General health perceptions	GH†	6*	Perceptions of overall health and illness
Parental impact-emotional	PE	3	Distress and worry experienced by parents concerning child's condition
Parental impact-time	PT	3	Limitations in personal time experienced by parents because of child's condition
Family activities	FA	6	Limitations and interruptions in usual family activities and family tension as a result of the child's health
Family cohesion	FC‡	1	Ability of family members to get along with one another
Global health	GGH†	1*	Overall health of the child
Global behavior	GBE†	1*	Overall behavior as compared with other children of the same age
Change in health	CH‡	1	Change in child's health as compared with 1 y ago

*The subscale BE also includes the single-item scale GBE and the subscale GH the single-item scale GGH leading to a total of 52 items counted for the table.

†A 4-week recall period was used for all concepts except for GH, FC, GGH, and GBE, for which "in general" is used instead.

‡The CH item was not used for this study.

Treatment satisfaction

The Life Quality Index (LQI) was developed for a study regarding PAD patients receiving IVIG infusion therapy at the clinic or at home.¹⁵ The LQI examines the respondent's perceptions of the impact of the IgG treatment on daily activities. The LQI is worded without reference to home- or clinic-based setting. The original LQI was slightly modified; ie, the wording "IVIG treatment" was changed to "SCIG treatment." Furthermore, in the version for the parents, the statements were modified to ask for the perceptions of the SCIG treatment in relation to "my child." The LQI consists of 15 statements, each rated on a 7-point Likert response scale. A maximum summary score of 105 indicates the highest possible satisfaction with factors such as independence, therapy convenience, social/school/work activities, and health and travel costs. In addition to the LQI, 2 preference items were used: "Which IgG therapy do you prefer?" (IVIG, SCIG, or no preference) and "Where do you prefer to receive your IgG therapy?" (in the hospital/in the doctor's office, at home, or no preference).

Translation of the questionnaires

When available, linguistically validated translations of the instruments were used. Where validated translations were not available, the translation process followed the standard for the translation of HRQOL instruments (forward-backward translation processes).¹⁶

Assessments

The CHQ-PF50 or the SF-36, the LQI, and questions about demographic background characteristics were completed at baseline.

At 6 and 10 months, the 2 "preference" items were added. The set of questionnaires was answered at the hospitals by the adult patients themselves or by the parents.

Statistical analysis

The primary analyses included the children ($n = 15$) and adults ($n = 32$) who were fully compliant with the study protocol. However, second-line analyses were also performed on the basis of the 2 entire populations of children ($n = 17$) and adults ($n = 41$) to explore whether the exclusion of noncompliant participants resulted in a biased comparison. The comparisons of the data at 10 months with baseline did not reveal relevant qualitative differences between the entire and the final populations with regard to any of the questionnaires. Thus, restriction of the analyses to the compliant participant populations did not lead to biased estimates.

The nonresponder rate to single items was very low (in total, 0.43%). Still, to handle missing data, 2 methods were used. If less than 50% of the responses within a single scale were missing for a respondent, item imputation was performed by mean value substitution as described in the scoring manuals.^{12,14} Otherwise, values were predicted by using an explicit regression model¹⁷ that included the previously observed scores on the scale for the individual as well as important covariates (age, country, route of previous IgG treatment, and number of SCIG infusions).

Data were analyzed with a repeated-measures model¹⁸ that assumes correlated assessments over time and normally distributed response variables. Separately for children and adults, 6- and 10-month assessments were compared with the patients' baselines. Statistical analysis was performed with SAS version 8.2 (SAS Institute Inc, Cary, NC).

TABLE III. Results of the CHQ-PF50 before and during SCIG self-infusions at home

Concept*	Baseline (mean $\pm$ SD)	6 mo (mean $\pm$ SD)	10 mo (mean $\pm$ SD)	P values	
				6 mo vs BL	10 mo vs BL
PF	90.4 $\pm$ 11.4	91.5 $\pm$ 25.8	90.4 $\pm$ 16.1	NS	NS
REB	79.5 $\pm$ 25.6	83.0 $\pm$ 32.8	95.6 $\pm$ 10.1	NS	.02
RP	85.6 $\pm$ 23.5	86.7 $\pm$ 30.3	92.2 $\pm$ 18.8	NS	NS
BP	80.0 $\pm$ 23.9	78.0 $\pm$ 22.7	88.7 $\pm$ 17.3	NS	NS
BE	67.3 $\pm$ 16.2	69.0 $\pm$ 20.0	72.4 $\pm$ 16.5	NS	NS
MH	70.8 $\pm$ 19.4	71.3 $\pm$ 20.0	76.3 $\pm$ 13.9	NS	NS
SE	80.5 $\pm$ 11.0	77.2 $\pm$ 16.2	82.2 $\pm$ 15.4	NS	NS
GH	36.1 $\pm$ 13.4	51.3 $\pm$ 15.3	53.7 $\pm$ 11.5	.01	.001
PE	52.8 $\pm$ 27.4	68.9 $\pm$ 27.4	72.8 $\pm$ 24.5	.05	.02
PT	64.4 $\pm$ 28.8	71.9 $\pm$ 26.8	81.5 $\pm$ 20.9	NS	.004
FA	68.1 $\pm$ 20.1	77.8 $\pm$ 21.2	85.6 $\pm$ 16.4	.04	.002
FC	67.3 $\pm$ 17.3	70.3 $\pm$ 21.0	76.0 $\pm$ 14.0	NS	NS
GGH	55.0 $\pm$ 23.6	77.8 $\pm$ 11.3	78.7 $\pm$ 14.6	.008	.01
GBE	69.7 $\pm$ 16.6	69.0 $\pm$ 22.8	69.7 $\pm$ 21.9	NS	NS

BL, Baseline; NS, not significant.

*Explanations of the abbreviations of the concepts are given in Table II. Higher scores indicate better physical or psychosocial functioning or less effect on the family situation because of a disease.

Ethics

All adult patients and the children's parents were given oral and written information in their own languages, and written informed consent was obtained from all study participants. The local ethics committee at each participating hospital approved the study before any patient was informed and enrolled.

RESULTS

HRQOL: CHQ-PF50

Significant improvements were found for 6 of the CHQ-PF50 subscales at 10 months compared with baseline. Between 47% and 87% of the 15 children showed an improvement of at least 5 points with regard to these scales. Four of these significant improvements were already seen after 6 months (Table III).

HRQOL: SF-36

The 22 adults on IVIG at enrollment reported significantly improved vitality (baseline mean, 62.8; 10-month mean, 70.2; $P = .04$), mental health (baseline mean, 87.5; 10-month mean, 94.3; $P = .05$), and social functioning (baseline mean, 77.7; 10-month mean, 83.2; $P = .01$) at 10 months. The proportion of IVIG adults with an improvement of at least 5 points was 50%, 32%, and 32%, respectively, for the 3 scales. The 10 adults on SCIG at enrollment reported high SF-36 scores already at baseline, and no significant changes were seen over time (data not shown).

TS: LQI

For the children, the total mean summary LQI score significantly improved from 73.4 ± 13.4 at baseline to 94.9 ± 8.7 at 10 months ($P = .0001$; Fig 1). For the adults

on IVIG therapy at enrollment, the total mean summary LQI score improved from 82.2 ± 15.0 to 93.7 ± 9.0 ($P = .0012$). Sixty percent of the children and 50% of the adults reported an increase of at least 10 points. The adults on SCIG therapy at enrollment reported a high total mean summary LQI score already at baseline (95.6 ± 10.7), and no significant change was seen over time (94.5 ± 8.8 at 10 months; Fig 1).

Preference items

All children and their parents and all 10 adults on SCIG therapy at enrollment reported that they preferred the SCIG self-infusions at home. Sixteen (73%) of the 22 adults on IVIG at enrollment reported that they preferred the SCIG self-infusions at home. Two reported that the continuation of SCIG therapy was most important, but they had no preference regarding setting. Two patients had no preference regarding the IgG administration route but wanted to continue with home therapy. One patient reported no preference regarding either IgG administration route or setting, and 1 patient preferred IVIG therapy at the hospital.

DISCUSSION

HRQOL is a subjective perception of the effect of health status (including disease and treatment) on physical, psychological, and social functioning and well-being.^{19,20} Children and adults with PAD have a chronic condition and in most cases are faced with the prospect of lifelong IgG treatment. Surprisingly, only 1 study¹¹ using standardized, validated, generic HRQOL instruments has been presented with patient-reported data regarding HRQOL in adults. In this study, the HRQOL and TS of children with PAD and their families have been addressed for the first time.

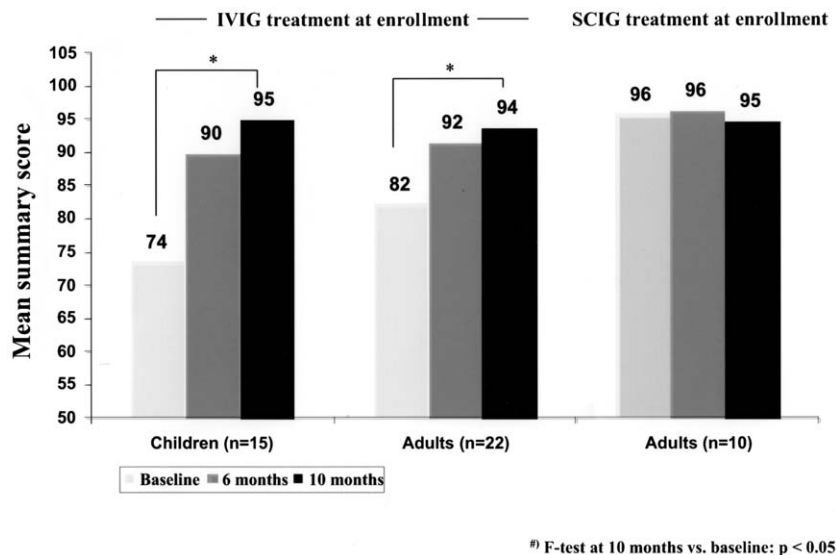


FIG 1. Life Quality Index scale (range, 15-105). A maximum summary score of 105 indicates the highest possible satisfaction with the effect of any IgG replacement therapy on factors such as independence, therapy convenience, social/school/work activities, and health and travel costs. Data are given as self-reported summary scores for children and adults at baseline and at 6 and 10 months. * $P < .05$ (F test at 10 months vs baseline).

The parents reported significant improvements for 6 of the 14 subscales in the CHQ-PF50. The improvements were seen in areas related to the children's social functioning and health, the parents' own life situation, and family functioning. After the introduction of the SCIG home-therapy regimen, the parents reported improved school and social functioning for their child (subscale role/social-emotional, behavioral) and improved overall health (global health); they also reported that the child now was as healthy as other children and that the child had a better resistance against infections (general health perceptions). Moreover, the parents had greater expectations for a healthier life of the child in the future (general health perceptions).

From this study, is it not possible to say whether the reported improvements in the children's health were primarily related to the use of the SCIG therapy itself, the switch to home therapy, or both. The main goal with any IgG replacement therapy is to achieve normalized serum IgG levels and, thereby, a reduced frequency and severity of infections. One inclusion criterion for the study was a serum IgG trough level of >5 g/L for at least 6 months before enrollment. In the children, the serum IgG trough levels ranged between 5.5 and 11.9 g/L at enrollment and remained high (data not shown). The stable day-by-day serum IgG concentrations demonstrated between SCIG infusions^{21,22} may have contributed to a better resistance against infections and, thereby, the better health status of the children. The SCIG administration route also avoids unphysiologically high serum IgG peak levels, as are commonly observed after IVIG infusions; these are suspected to trigger systemic side reactions such as headache. Another benefit from the

home-therapy regimen itself was the reduced number of visits to the hospital for the PAD children and a decreased risk for the children to acquire infections. This may contribute to the reported improved health of the PAD children and may also reduce the parents' anxiety that their child may become infected. Indeed, in this study it was found that the introduction of the SCIG home therapy made the parents feel less worried or concerned regarding their child's physical health and emotional well-being (subscale parental impact-emotional).

The parents also reported that the introduction of the home therapy resulted in less limitation in personal time for their own needs (parental impact-time). Moreover, the home-therapy regimen positively influenced the entire family situation, eg, fewer restrictions and interruptions in the usual family activities (family activities). Home therapy has been considered especially important in pediatric immunodeficiency care because it saves the families the trips to the hospital,⁴ and families have reported that they prefer the shorter, more frequent infusions at home to the more disruptive and lengthy visits to a hospital every third to fourth week as required by IVIG infusions.⁵

For the adults on IVIG therapy at enrollment, improvements in HRQOL as measured by the SF-36 were also seen (vitality, mental health, and social functioning) after the switch to SCIG home therapy. This was in contrast to the adults already on SCIG home therapy, in whom high scores for these 3 scales were already seen at enrollment. The vitality scale captures the subjective well-being in relation to energy level and fatigue, the mental health scale captures different aspects of psychological well-being, and the social functioning scale captures both the quantity

and quality of social activities.¹⁴ It has previously been shown that adult patients with common variable immunodeficiency who are not yet treated with IgG replacement therapy report significantly pronounced fatigue, restrictions in social and leisure activities, and poorer psychological well-being compared with healthy individuals.¹¹ Also, adults on hospital-based therapy with adequate dosages of IVIG infusions or intramuscular IgG injections reported significantly decreased physiological well-being and pronounced fatigue compared with healthy individuals. The introduction of SCIG home therapy was, in both the untreated and the previously IVIG-treated or intramuscular IgG-treated adults, found to result in a significant improved HRQOL and decreased fatigue.¹¹ It has been stated by the patients that the introduction of home therapy leads to independence, a sense of freedom and flexibility, and a reduced sense of being sick or disabled.²³ Introduction of home therapy programs seems to have a major beneficial effect on the patients' psychological well-being and vitality. This in turn may lead to an increased courage for welcoming social contacts and activities—something otherwise avoided by PAD patients because of tiredness and fear of acquiring infections.¹¹

The increased vitality reported in both this study and in the previous HRQOL study¹¹ after the introduction of the weekly SCIG therapy is of interest in relation to the ongoing discussion regarding the possible benefit of the stable between-infusion serum IgG levels seen during SCIG therapy.^{21,22} It is known that the use of monthly IVIG therapy results in fluctuations in serum IgG concentrations,²⁴ and patients often complain of increased tiredness and worsened well-being in the week before the next infusion. The increased infusion frequency with the weekly SCIG therapy has been found to result in a trend to a higher IgG trough level⁷ and a day-by-day serum IgG curve that better corresponds to the normal endogenous IgG production.²² The stable serum IgG level between weekly SCIG infusions may indeed be one contributing factor to the improved vitality reported by the patients.

The introduction of the home-therapy program also led to increased TS, as measured by the LQI, for children and adults switching from hospital-based to home-based therapy. The adults on SCIG home therapy at enrollment already reported a high total mean summary LQI score at baseline. The LQI showed that home therapy resulted in greater independence, with less disruption of daily activities; less effect on school, work, and social activities; freedom to travel; better therapy convenience; comfort; treatment flexibility; and pleasantness of treatment atmosphere. The concept of feeling able to control a treatment is important for the patient because a sense of active participation leads to greater compliance and improved medical outcome.¹⁵

Also, home-based IVIG therapy is a patient-appreciated option in some countries. In a study from the United States, it was shown that the switch from hospital-based IVIG to home-based IVIG therapy improved the TS of the

included children and adults.¹⁵ However, different patient selection criteria must be used for IVIG self-infusions at home, and this reduces the number of individuals who can benefit from home therapy.

The home-therapy regimen, whether SCIG or IVIG, has also a beneficial effect on the direct and indirect costs of the society and of the individual patient and family. For the families in this study, the child and at least 1 parent had to visit the hospital for IVIG therapy an average of every third week, ie, seventeen 1-day visits per year. For the 15 children in this study alone, the production loss for the accompanying adults amounted to 225 days. The parents may also have to take time off from work with salary reductions and also pay for the travel costs and possible fees at the hospital. Once in home therapy, no time off from school for the child or work for the parent is needed. Instead the infusion can be given at a suitable time for the family, for example, during the evening when watching television, when the child is busy playing, or during dinner. It has been shown that SCIG therapy at home substantially reduces society and health-care costs³ and cuts the direct and indirect costs of the patients by half.²⁵

The study design was derived from the European Committee for Proprietary Medicinal Products guidelines for intravenous²⁶ and subcutaneous and intramuscular²⁷ use of immunoglobulins. Both guidelines recommend that IgG replacement therapy be studied in a longitudinal design for at least 6 months. To have more reliable data, we expanded the European Union recommendation by treating more patients and for 10 months with weekly SCIG. The study was designed as an open prospective evaluation that used each participant as his or her own control in comparing baseline HRQOL data with the data reported at the final evaluation after 10 months. The follow-up time for this study was 10 months, and this must be considered a short period in which to study the effect of a treatment on HRQOL and daily activities. However, already after 6 months the parents and the adult patients reported significant improvements in HRQOL. We cannot completely rule out the possibility that the improvements in HRQOL and TS were, to some extent, results from study effects. However, most likely, the reported changes can be attributed to the switch from the hospital-based to the home-based therapy; otherwise, the patients who had already been on SCIG before enrollment in the study should also have exhibited a further improvement with regard to their HRQOL and TS, but this did not occur.

For children and adults with PAD, lifelong IgG replacement therapy aims at reducing the frequency and severity of infections and the subsequent fatigue and lack of energy. A successful IgG treatment and support should provide the patient with a feeling of increased resistance to infections and, thereby, the courage, strength, and willingness to participate in social and family activities. In this study, it was found that several aspects of the HRQOL and the TS improved when children and adults with PAD changed from a staff-run, hospital-based IVIG therapy program to a staff-supported, patient- or parent-run, home-therapy program with SCIG self-infusions. A successful

home-therapy regimen must be based on interactive patient/family education programs and continuous support.^{23,28,29} The easy SCIG administration technique gives most adult patients and children or parents the opportunity to manage their own IgG treatment. On the basis of the results from this study and previous evaluations of the SCIG administration route showing safety,²⁻¹⁰ normalized serum IgG trough levels,^{2,3,6,7,10,21,22} protection against infections,⁷ patient preference for home therapy,^{4,5,11,15,23} and the easy infusion technique, SCIG home therapy is strongly advocated as a therapeutic alternative for adults and children in need of lifelong IgG replacement therapy.

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