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Reduction of Infusion Time Using a 10% Intravenous Immunoglobulin Formulation With a 15-Minute Rate Escalation Protocol During Staffing Shortages Due to COVID-19

Barbara Prosser, RPh • Timothy P. Walton, MHS, CCRP • Christine Miller, PharmD

ABSTRACT

The COVID-19 pandemic changed home infusion nursing dramatically by increasing demand for home infusion nurses while decreasing their availability. Home infusion of intravenous immunoglobulin (IVIg) is an option for treatment of numerous conditions and requires considerable infusion time. Use of a higher-concentration IVIg product and shorter escalation increments may decrease required infusion time. The authors conducted a retrospective database analysis that identified 23 patients receiving IVIg before transitioning to a 10% IVIg product with a 15-minute rate escalation protocol (Gammaplex 10% IVIg) and evaluated the total infusion time before and after the transition. Among the 23 who received IVIg, the mean ± SD IVIg dose per dosing cycle before transitioning was 1.2 ± 0.7 g/kg given in 1 to 5 infusions per cycle. The mean ± SD time per infusion was 2.8 ± 0.8 hours before the transition and 2.6 ± 0.7 hours per infusion after the transition. The infusion time decreased after transition in 13 patients (56.5%), did not change in 5 patients (21.7%), and increased in 5 patients (21.7%). Nurse education on IVIg rate escalation may facilitate faster achievement of the maximum safe infusion rate and reduce infusion times. A trial transition to this 10% IVIg product with a 15-minute rate escalation protocol may also reduce infusion times.

Key words: immunoglobulin, infusion rate, infusion time, intravenous, IVIg

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BACKGROUND

Home infusion is an important site of care option for many patients with chronic conditions that require long-term infusion therapy. The COVID-19 pandemic has had a profound effect on home infusion nursing. Many organizations are transitioning from in-clinic infusions to home infusions by specialty pharmacy nurses to decrease the risk of exposing patients to COVID-19, particularly patients who are immunocompromised.[1-5] In addition, the COVID-19 pandemic has increased the demand for home nursing visits while increasing demand for skilled nurses to care for patients with COVID-19, thereby decreasing nursing availability due to the multiple effects of COVID-19 on individual nurses. In this situation, practice changes that reduce the time required for home infusions may benefit patients, nurses, and health care organizations by optimizing patient convenience, tolerability, adherence, and quality of life while reducing costs and health care use. In addition, more efficient use of home nursing time may allow more patients to be managed at home, increasing the availability of scarce resources in hospitals and other health care facilities.

Administration of immunoglobulin (Ig) therapy is one of many services performed by home infusion nurses. Ig therapy is used in treating a broad spectrum of conditions, such as primary and secondary immunodeficiency syndromes and autoimmune disorders. Ig products are manufactured from plasma pooled from several thousand donors and contain a polyclonal, polyspecific mixture of antibodies, primarily immunoglobulin gamma. Ig therapy is often administered parenterally by intravenous infusion (IVIg), with the dose and schedule individualized for each patient and disease state, and the infusion is typically administered in outpatient or home settings. The infusion rate is a key determinant of the overall infusion time. IVIg administration is typically initiated at a low infusion rate, which is increased at regular intervals up to the maximum tolerated rate or the maximum rate recommended by the product labeling. Adverse drug reactions that occur during the infusion can usually be managed by reducing the infusion rate, which prolongs the overall infusion time. Studies involving IVIg 10% formulations have demonstrated reductions in infusion time and cost compared with IVIg formulations at lower concentrations.[6-9] Use of a 15-minute rate escalation protocol (15 min between escalations) may also allow shorter IVIg infusion times, depending on individual tolerability. However, in current routine practice, infusion protocols with short intervals between escalations may not be considered or prescribed, potentially resulting in infusion times that are longer than necessary for patients.

This retrospective analysis of a home-infusion database was conducted to evaluate the effect of a 10% IVIg product with a 15-minute rate escalation protocol (Gammaplex 10% IVIg, Bio Products Laboratories, Elstree, United Kingdom) versus other Ig formulations on the time required for home infusions. A post hoc analysis of infusion rates was conducted to evaluate the potential for increasing the infusion rate per the approved product labeling to further decrease the time required. Gammaplex is the only IVIg product approved for administration with a 15-minute rate escalation protocol, beginning with the initial infusion, and for following maintenance infusions, for both primary immunodeficiency (PI) and chronic immune thrombocytopenic purpura.

METHODS

This was a retrospective study by a multidisciplinary team using deidentified patient data from a proprietary clinical outcomes database of nursing and pharmacy services provided by a specialty pharmacy (SoleMetrics, Soleo Health, Frisco, TX). The team searched the database to identify all patients who received Gammaplex 10% IVIg after previously receiving other IVIg products during the 30-month period between January 1, 2018, and June 30, 2020. To ensure patient anonymity, identifying information was omitted from the results of the database search. The specialty pharmacy considered several factors when identifying candidates for a transition to Gammaplex 10% IVIg, including the presence of comorbid hypertension, renal disease, cardiovascular disease, and other underlying conditions; the patient's previous experience with Ig-related adverse drug reactions; and financial or logistical considerations (eg, cost or availability of IVIg products). All IVIg products were administered according to the specialty pharmacy standards of practice, which detail infusion procedures, vital sign monitoring frequency, and management of potential infusion reactions. Review and approval by an institutional review board was not required because this was a retrospective study using deidentified data.

Data collected included the IVIg dose, dosing frequency, mean infusion duration before and after the transition to Gammaplex 10% IVIg, and the rate escalation protocol and maximum infusion rate achieved after the transition. Ig infusion times before the transition were calculated and compared with the infusion times after the transition, allowing estimates of the change in time required per infusion and per dosing cycle. The infusion times were calculated based on documented start time, rate escalation period, and disconnect times and excluded the time spent on the initial assessment and general documentation. Any interruptions in the infusion, such as for management of adverse reactions or disconnects for toilet breaks, were counted as part of the total infusion time. The dosing cycle is the full sequence of infusions on consecutive days when the patient dose is divided across several days. The analysis was stratified post hoc by the effect of the transition on the total infusion time (decrease, no change, or increase). This allows for estimation of the effects of a transition to Gammaplex 10% IVIg in real-world practice, where the transition would be initiated on a trial basis and only continued if it proved to be beneficial.

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Cost analyses are based on nursing infusion time only, which was estimated at $90 per hour (the average cost for the specialty pharmacy conducting the study).

RESULTS

A total of 23 patients met the inclusion criteria and were included in the analysis. These patients represent a spectrum of IVIg doses and regimens. Table 1 summarizes Ig regimens and infusion times before and after the transition. The mean total Ig dose per cycle (± SD) was 1.2 ± 0.7 g/kg (range, 0.28–2.22 g/kg) given in 1 to 5 infusions per cycle on a variety of schedules with previous IVIg products. The corresponding times required for infusions (mean ± SD) were 2.8 ± 0.8 hours per infusion (range, 1.5–4.8 h per infusion) and 7.3 ± 4.9 hours per cycle (range, 1.5–17.5 h per cycle). After the transition to Gammaplex 10% IVIg, the time required for infusions was 2.6 ± 0.7 hours per infusion (range, 1.0–4.0 h per infusion) and 6.7 ± 4.8 hours per cycle (range, 1.4–15.0 h per cycle). A single patient (patient 2) experienced a substantial reduction in body weight (from 87.6 kg to 72.6 kg) due to an unrelated illness and had the Ig dose reduced (from 0.4 g/kg over 5 d to 0.2 g/kg over 5 d) from initial treatment with the prior IVIg to subsequent treatment with Gammaplex 10% IVIg, respectively. To minimize the confounding effect of these changes on this patient's infusion times from pretransition to posttransition, this patient's infusion time before the transition to Gammaplex was extrapolated to the posttransition body weight and dose, and the extrapolated infusion time was used in all subsequent analyses.

The infusion time decreased after the transition (Table 1) in 13 patients (56.5%), did not change in 5 patients (21.7%), and increased in 5 patients (21.7%). The mean change in infusion time from the previous IVIg therapy to Gammaplex 10% IVIg was –0.2 ± 0.6 hours per infusion (range, –1.4 to 1.3 h per infusion) and –0.6 ± 2.2 hours per cycle (range, –4.7 to 6.3 h per cycle). Table 2 summarizes the effect of the transition on infusion times for each group. Note that a negative change indicates a time savings. Figure 1 depicts the results for each patient (see Supplementary Table 1 at http://links.lww.com/JIN/A103 for additional details).

Key factors that affect IVIg infusion times are the rate escalation schedule and the maximum infusion rate reached. The current analysis included an exploratory post hoc analysis of these factors. Dosing started at 0.5 mg/kg/min and was increased at intervals of 15 to 60 minutes until the maximum tolerated infusion rate was reached. The details of the rate escalation process were individualized per patient based on tolerability and other factors. Table 3 provides information on dosing protocols for each patient. In 13 (56.5%) of 23 patients, the rate escalation increment decreased from 30 to 15 minutes. The average maximum rate was 4.8 ± 1.8 mg/kg/min (range, 1.4–10.0 mg/kg/min). In comparison, the maximum infusion rate specified in the Gammaplex 10% IVIg product labeling is 8.0 mg/kg/min (0.08 mL/kg/min). Of the 23 patients whose maximum infusion rate was documented, 1 patient (4.3%) achieved the maximum rate, 5 patients (21.7%) achieved a rate >6 mg/kg/min (75% of the maximum), and 15 patients (65.2%) achieved a rate >4 mg/kg/min (50% of the maximum). No adverse reactions were reported during infusions after the transition among the patients whose infusion times increased. Three of these patients had no change in the maximum infusion rate. Two patients were known to have had interruptions in the infusion: 1 patient to administer 500 mL of hydration and 1 patient for a toilet break.

DISCUSSION

Transitioning from other Ig therapies to this 10% IVIg product with a 15-minute rate escalation protocol led to decreases in the total time required for infusion in the majority (56.5%) of the 23 patients evaluated in this retrospective study. The increased infusion times observed for 21.7% of the patients were due to nursing assessment of tolerability before the transition, which prompted a decrease in the infusion rate. However, no adverse drug reactions were reported for these patients after the transition.

Review of the literature identified 4 previous studies that evaluated the infusion times of various IVIg formulations. In 2021, Van Ham et al[8] reported a comparison of administration of 5% Multigam to 10% Multigam in a day clinic in Belgium for patients with a secondary immunodeficiency (Biotest AG, Dreieich, Germany). They found a significant decrease in infusion time (4.92 to 2.29 h, $P < .0001$), along with other measures of health care resource use. However, adverse event rates increased from 0 to 0.43 per patient.[8] Bauer et al[9] evaluated rapid infusion of Gammaplex 10% IVIg over 11 months in 49 patients and found an estimated time savings of 2.4 hours per infusion, with an associated decrease of $151.61 in nursing costs. A total of 38 adverse reactions, of which 37 were mild/moderate, were reported by 14 patients.[9]

Connolly and Simoens[7] compared a 10% IVIg formulation (Kiovig, Baxter AG, Vienna, Austria) with two 5% IVIg formulations (Multigam and Sandoglobulin, CSL Behring LLC, King of Prussia, PA) for the treatment of PI in Belgium in 2011 using an economic model that calculated the cost of a single infusion based on the costs of the IVIg medication, overhead, pharmacy, adverse events, nursing, and patient loss of productivity. The study found decreases in nursing time for the 10% IVIg preparation versus the 2 comparators, with a decrease in cost ranging from €56 to €101 per infusion.[7]

Kallenberg[6] reported an observational study conducted in the Netherlands in 2007 that compared a 10% IVIg formulation (Kiovig) with a lyophilized 6% IVIg formulation (Immunoglobuline IV, Sanquin Blood Supply Foundation, Amsterdam, the Netherlands) in 15 patients with primary

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TABLE 1

Ig Dose, Regimen, and Infusion Time Before and After the Transition to the 10% IVIg Product Evaluated in This Study

ID	Ig Therapy Prior to Transition to Gammaplex 10% IVIg	Infusion Time (h)		Ig Therapy After Transition to Gammaplex 10% IVIg	Infusion Time (h)		Change in Infusion Time (h)	
	Ig dose, g/kg	Per infusion	Per cycle	Ig dose, g/kg	Per infusion	Per cycle	Per infusion	Per cycle
1	0.56 g/kg over 1 d, every 3-4 wk	2.5	2.5	0.56 g/kg over 1 d, every 3-4 wk	1.4	1.4	−1.1	−1.1
2[a]	1.03 g/kg over 5 d, once	1.9	9.4	1.05 g/kg over 5 d, once	1.0	5.0	−0.9	−4.4
3	2.22 g/kg over 3 d, once	4.3	12.8	2.29 g/kg over 3 d, once	3.4	10.3	−0.8	−2.5
4	1.03 g/kg over 2 d, every 6 wk	3.4	6.7	1.03 g/kg over 1 d, every 4 wk	2.0	2.0	−1.4	−4.7
5	2.20 g/kg over 5 d, once	2.5	12.5	2.20 g/kg over 5 d, every 4 wk	2.3	11.3	−0.3	−1.3
6	2.12 g/kg over 5 d, once	3.0	15.0	2.12 g/kg over 5 d, once	2.5	12.5	−0.5	−2.5
7	1.92 g/kg over 3 d, every 6 wk	4.8	14.3	1.92 g/kg over 3 d, every 6 wk	4.0	12.0	−0.8	−2.3
8	0.53 g/kg over 1 d, every 6 wk	4.0	4.0	0.53 g/kg over 1 d, every 6 wk	3.3	3.3	−0.8	−0.8
9	0.47 g/kg over 1 d, every 2 wk	3.0	3.0	0.47 g/kg over 1 d, every 2 wk	2.8	2.8	−0.3	−0.3
10	2.09 g/kg over 5 d, once	3.5	17.5	2.09 g/kg over 5 d, once	3.0	15.0	−0.5	−2.5
11	0.93 g/kg over 2 d, every 4 wk	3.0	6.0	0.93 g/kg over 2 d, every 4 wk	2.8	5.5	−0.3	−0.5
12	1.10 g/kg over 3 d, every 4 wk	3.0	9.0	1.10 g/kg over 3 d, every 4 wk	2.5	7.5	−0.5	−1.5
13	0.53 g/kg over 1 d, every 30 d	2.8	2.8	0.53 g/kg over 1 d, every 4 wk	2.5	2.5	−0.3	−0.3
14	1.95 g/kg over 3 d, once	3.3	9.8	1.95 g/kg over 3 d, once	3.3	9.8	0.0	0.0
15	1.93 g/kg over 3 d, every 30 d	2.5	7.5	1.89 g/kg over 3 d, every 30 d	2.5	7.5	0.0	0.0
16	0.41 g/kg over 1 d, every 3 wk	2.0	2.0	0.41 g/kg over 1 d, every 3 wk	2.0	2.0	0.0	0.0
17	0.31 g/kg over 1 d, every 30 d	1.5	1.5	0.31 g/kg over 1 d, every 30 d	1.5	1.5	0.0	0.0
18	0.56 g/kg over 1 d, every 3 wk	2.8	2.8	0.56 g/kg over 1 d, every 3 wk	2.8	2.8	0.0	0.0
19	0.28 g/kg over 1 d, every 30 d	1.8	1.8	0.28 g/kg over 1 d, every 30 d	2.0	2.0	0.3	0.3
20	2.15 g/kg over 5 d, once	2.5	12.5	2.15 g/kg over 5 d, once	2.8	14.2	0.3	1.7
21	1.03 g/kg over 1 d, every 3 wk	3.1	3.1	1.03 g/kg over 1 d, every 3 wk	3.5	3.5	0.4	0.4
22	0.97 g/kg over 2 d, every 30 d	2.0	4.0	0.97 g/kg over 2 d, every 30 d	2.8	5.5	0.8	1.5
23	1.86 g/kg over 5 d, every 5 wk	1.8	8.8	1.86 g/kg over 5 d, every 5 wk	3.0	15.0	1.3	6.3
Mean ± standard deviation		2.8 ± 0.8	7.3 ± 4.9		2.6 ± 0.7	6.7 ± 4.8	−0.2 ± 0.6	−0.6 ± 2.2

Abbreviations: g, gram; ID, identifying number; Ig, immunoglobulin; IVIg, intravenous immunoglobulin; kg, kilogram.

[a]The pretransition IVIg infusion time for patient 2 was extrapolated based on posttransition weight and IVIg dose to minimize confounding by a substantial decrease in body weight and IVIg dose. See the Results section for details.

TABLE 2

Time Per Infusion Before and After the Transition to the 10% Intravenous Immunoglobulin Product Evaluated in This Study, by the Overall Effect on Infusion Time

Effect on Infusion Time	Time Per Infusion, h (mean ± SD)			Impact on Home Infusion Nursing Costs, USD (mean ± SD)[a]
	Before Transition	After Transition	Change	
Decrease (n = 13)	3.2 ± 0.8	2.6 ± 0.8	–0.6 ± 0.3	$–56 ± 32
No change (n = 5)	2.4 ± 0.7	2.4 ± 0.7	0.0 ± 0.0	None
Increase (n = 5)	2.2 ± 0.6	2.8 ± 0.5	0.6 ± 0.4	$54 ± 37
All patients (n = 23)[b]	2.8 ± 0.8	2.6 ± 0.7	–0.2 ± 0.6	$–20 ± 54

Abbreviation: SD, standard deviation.

[a]Estimated based on the time required for the infusion using a nursing cost of $90/h; the home infusion provider's actual costs are calculated in whole-hour increments and may differ from the above.

[b]This row is the value for all 23 patients; thus, the 13 patients with a decrease in infusion time are weighted more heavily than the 5 patients with no change or the 5 patients with an increase.

immunodeficiency. Use of the 10% IVIg formulation was associated with a 44% increase in the infusion rate, a 51% decrease in the infusion time (from 104 to 51 min), and a decrease in the rate of drug-related adverse events. The decreased infusion time corresponded to a €17.74 cost savings in nursing time, with additional savings for pharmacy time and bed occupancy.[6] Infusion time is an important parameter for both patients and the health care system because of its potential effects on patient satisfaction and quality of life and on health care resource use and costs. Given the limited evidence available, additional research on strategies for decreasing Ig infusion times is warranted. Although the current study focused on product formulations and infusion times in home infusions during the COVID-19 pandemic, other strategies, such as multipatient outpatient infusion suites, may be useful in reducing infusion times and health care use and costs.

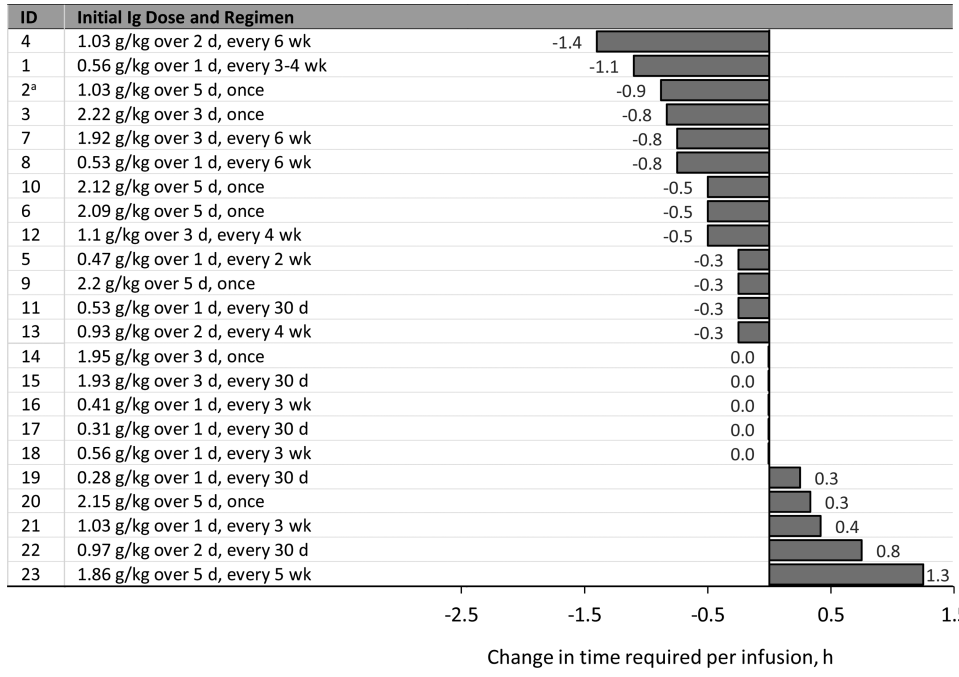

Figure 1 Change in time per infusion for patients transitioning from a different IVIg product to the 10% IVIg product studied. Abbreviations: *ID, identifying number; IVIg, intravenous immunoglobulin.*

TABLE 3

IVIg Maximum Infusion Rate and Rate Escalation Increment

ID	Previous IVIg Highest Rate Reached		Rate Escalation Increment (min)	Gammaplex 10% IVIg Highest Rate Reached		% of Maximum Rate[a]	Rate Escalation Increment (min)	Rate Difference		Change in Rate Escalation Increment (min)
	mL/h	mg/kg/min		mL/h	mg/kg/min			mL/h	mg/kg/min	
1	190	5.06	15	375	9.98	124.8%	15	185	4.93	0
2	183	4.20	30	264	6.06	75.8%	15	81	1.86	–15
3	300	3.70	30	370	4.56	57.1%	15	70	0.86	–15
4	315	4.16	15	315	4.16	52.0%	15	0	0.00	0
5	146	5.36	30	168	6.17	77.2%	15	22	0.81	–15
6	144	4.07	30	142	4.01	50.2%	15	–2	–0.06	–15
7	80	1.42	30	80	1.42	17.8%	15	0	0.00	–15
8	120	3.53	30	135	3.97	49.6%	15	15	0.44	–15
9	237	6.22	15	170	4.46	55.8%	15 to 30	–67	–1.76	0 to 15
10	183	4.26	15	250	5.81	72.7%	15	67	1.56	0
11	317	4.48	30	254	3.59	44.8%	15	–63	–0.89	–15
12	240	3.68	30	253	3.88	48.4%	15	13	0.20	–15
13	235	6.96	30	235	6.96	87.0%	30 to 45	0	0.00	0 to 15
14	234	4.00	30	229	3.91	48.9%	15	–5	–0.09	–15
15	229	2.89	30	225	2.84	35.5%	15	–4	–0.05	–15
16	400	6.13	20 to 30	320	4.90	61.3%	20	–80	–1.23	0 to -10
17	200	3.42	30	Not documented			30			
18	275	5.16	30	220	4.12	51.6%	15	–55	–1.03	–15
19	227	4.28	30	214	4.03	50.4%	15	–13	–0.24	–15
20	222	5.30	30	222	5.30	66.2%	30	0	0.00	0
21	400	6.87	15 to 20	400[b]	6.87	85.8%	20	0	0.00	0 to 5
22	270	5.80	30	261	5.61	70.1%	15	–9	–0.19	–15
23	150	2.66	30 to 60	150	2.66	33.3%	30 to 60	0	0.00	0

Abbreviations: ID, identifying number; IVIg, intravenous immunoglobulin; kg, kilogram; mg, milligram; mL, milliliter.
[a]Maximum rate: 8 mg/kg/min per product labeling.
[b]Some infusion pumps have a maximum rate of 400 mL/h; this may have been the limiting factor determining this patient's maximum infusion rate.

One key determinant of the total infusion time is the maximum infusion rate reached. In the current study, a considerable minority of the patients (7/23, 30%) had maximum rates <4 mg/kg/min (less than half of the maximum approved rate). In contrast, during the pivotal clinical trial of Gammaplex 10% IVIg, 84.7% (210/248) of infusions in both adult and pediatric patients reached the maximum infusion rate.[10] This suggests an opportunity to decrease infusion times considerably for patients who are not achieving the maximum rate. Reasons for the difference between infusion rates in routine clinical practice versus the clinical trial setting are not fully understood, although the need for additional training in IVIg infusion procedures may have contributed. Note that transitioning did not result in shortened infusion times in every case; some patients had increased infusion times. As with other aspects of Ig therapy, decisions about the transition should be individualized for each patient. In practice, the transition can be initiated on a trial basis and continued only when clear benefits are observed.

Operationally, reducing infusion times may reduce costs by reducing nursing time. In the current study, reductions in infusion time for the majority of patients who transitioned to Gammaplex 10% IVIg corresponded to an average reduction in nursing costs of $56 (SD ± $32) per infusion among patients whose infusion time decreased after the transition (Table 2). Although the outcome of a transition will vary for different practices and patient populations, these results suggest that a trial transition could provide substantial reductions in infusion times and costs for many patients, especially if the maximum infusion rate is tolerated. The reduction in infusion time may also impact other operational parameters. Nurses may be able to use the time for other essential tasks, such as visit documentation and

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patient care, and the additional time may improve staffing flexibility so that the organization is better able to manage staffing issues arising from the COVID-19 pandemic.

Limitations

This was a nonrandomized, retrospective analysis with a small number of patients. Also, documentation of infusion procedures was limited, so increases in infusion times may not have been drug related.

CONCLUSION

Transitioning from other IVIg therapies to this 10% IVIg product with a 15-minute rate escalation protocol reduced home infusion times for most patients, potentially reducing health care use and cost while improving patient satisfaction and quality of life. Many patients receive IVIg at considerably less than the maximum rate, and carefully increasing the infusion rate for these patients may provide similar benefits. Additional research into strategies for reducing IVIg infusion times is needed and will probably benefit patients and further reduce health care utilization and costs. For patients receiving Ig therapy via home infusions, a transition to a 10% IVIg product with a 15-minute rate escalation protocol may reduce the time required for infusions, thereby improving operational and scheduling flexibility and providing potentially significant cost savings.

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