Case Study: Successful transition to ASCENIV therapy with improved PROMs

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Objective

The purpose of this case study review was to demonstrate the use of patient reported outcome measures (PROMs) to evaluate the effectiveness of therapy success and outcomes in a patient with primary immunodeficiency.

Background

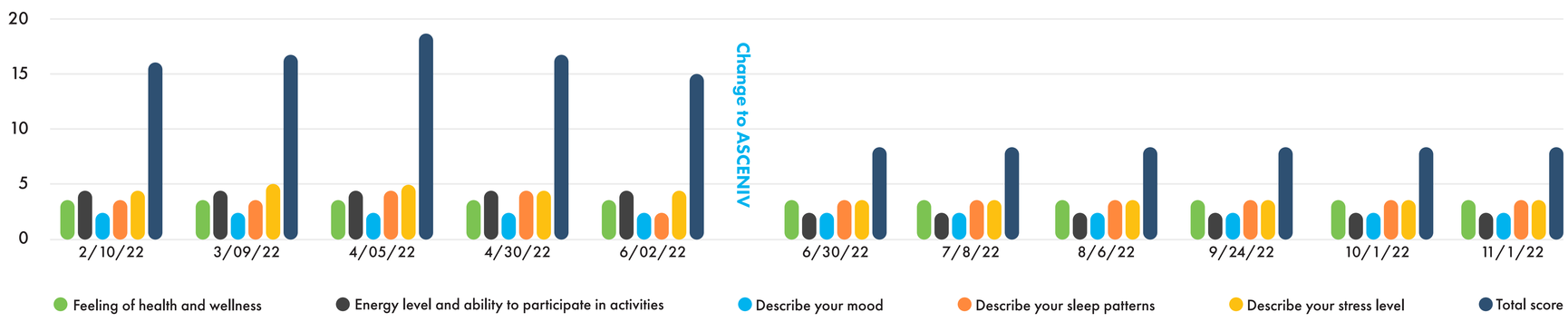
A 74-year-old Caucasian woman receives IVIg for the treatment of selective deficiency of immunoglobulin G [IgG] subclasses, ICD-10 D80.3. Past medical history included chronic obstructive lung disease and hypothyroidism. After 4 months of receiving IVIg therapy in the home, the patient was transitioned to another IVIg product, ASCENIV, for the continued treatment of her condition. A retrospective review of her medical records was performed by a multidisciplinary team from the start of care to current status. The review included customized clinical assessments specific to primary immunodeficiency, wellness, and fatigue that were performed by the specialty infusion pharmacy, as reported through the proprietary clinical outcomes program SoleMetrics®. The review also included progress notes, nursing assessments, and hospital and physician office visit notes.

Methods

The patient assessment and completion of select PROMs were completed prior to each dispense of the medication or at the time of a home infusion nursing visit. Wellness was assessed using the Soleo Health Wellness scale and an immunology disease-specific assessment. The Modified Rasch-built Fatigue Severity Scale (mFSS) was used to track fatigue and lifestyle changes related to the disease state.

Soleo Health Wellness Scale

	Score				
	1	2	3	4	5
Energy Level	Lots of energy and can do the things I want to do	Can do most things, may need to rest at times	Normal level of energy	Feel tired most of the time, spend a lot of time sitting and not engaging in activities	Staying in bed most of the day due to fatigue, tired all day
Mood	In a great place and feel positive	Good mood most of the time	Feel even tempered	Feel blah some of the time, sometimes feel cranky	Depressed all of the time, irritable and annoyed with others
Sleep Patterns	Great restful sleep	Good sleep	No real problems	Have problems falling asleep or staying asleep	Insomnia
Stress Level	Very relaxed, feel at peace	Relaxed	Normal stress level and feeling calm	Somewhat stressed	Very stressed
Overall Health and Wellness	Feel great	Feel good	Feel Okay	Feel bad	Feel bad all the time



Modified Rasch-built Fatigue Severity Scale (mFSS)
(Lower score corresponds to better quality of life)

	7. Fatigue interferes with my work, family, or social life	How many days were you not able to exercise?
02/10/2022	1	Patient Did Not Answer
03/09/2022	3	Patient Did Not Answer
04/05/2022	3	Unable to exercise
04/30/2022	3	Unable to exercise
06/02/2022	3	Unable to exercise
Change to ASCENIV		
06/30/2022	Patient Did Not Answer	4
07/08/2022	Patient Did Not Answer	4
08/06/2022	2	4
09/24/2022	2	4
10/01/2022	2	>5
11/01/2022	2	Patient Did Not Answer

	Activity Related Comments
02/10/2022	No Comments
03/09/2022	No Comments
04/05/2022	No Comments
04/30/2022	No Comments
06/02/2022	No Comments
Change to ASCENIV	
06/30/2022	No Comments
07/08/2022	Able to ambulate outside and enjoy watching summer activities. Went to camping resort with son and enjoyed barbecue outside.
08/06/2022	Family gatherings have been tolerated
09/24/2022	No Comments
10/01/2022	Patient has been able to tolerate social gatherings and longer periods of ambulation without severe fatigue or dyspnea.
11/01/2022	Patient just returned from summer vacation, states was able to enjoy

Summary

The purpose of this case study is to highlight the successful transition from a previous prescribed IVIg to ASCENIV therapy. Wellness was based on 5 questions related to overall wellness, mood, energy, sleep patterns and stress. Other factors used were a subjective statement by the patient, "How are you feeling today," emergency department and hospitalization records, reported infections, and medication changes. While on the previous IVIg regimen, the patient reported an average wellness score of 16.6 compared to an average of 13 while on ASCENIV. Additionally, while on ASCENIV the patient reported zero infections, zero emergency or hospital visits, and improvement in the ability to exercise and participate in family and social activities. The unique source plasma for ASCENIV, which specifically contains neutralizing antibodies to respiratory syncytial virus, has the potential to improve outcomes in patients with poor response to other IVIg therapies.

Conclusion

After 6 months of ASCENIV therapy, the patient showed significant improvement in her overall wellbeing and response to therapy.

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