Health-Related Quality of Life in Patients with Primary Immunodeficiency and Concomitant Mental Health Issues

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Introduction

Primary immunodeficiency disorders (PIDD) affect approximately 1 in 1200 people in the United States[1]. One common therapy for this disease is immunoglobulin (Ig) therapy, which requires lifetime treatment to manage symptoms and prevent infections in patients with PIDD[2]. Forty-two percent of intravenous (IVIg) patients and 93% of subcutaneous (SCIg) patients in the US receive Ig therapy in the home.

Almost one in five US adults live with a mental health disorder, including depression, bi-polar disorder and anxiety[3]. Treatments for mental health disorders can include psychotherapy, medication, and psychosocial treatments[4]. Similarly to PIDD, treatment for these disorders are required for life due to the persistence of these illnesses[5].

When examining patient quality of life (QOL) in PIDD, many survey questions focus on whether the patient's illness impacts their mental and physical health. However, surveys such as the SF-36 ask patients to look at their health as a whole[6], which does not exclude other comorbidities from playing a role in patient responses. Thus, it is difficult to isolate the degree to which PIDD alone is affecting QOL and mental and physical health.

Lastly, medication adherence can be affected by a number of factors. Patients with mental health disorders are known to be a risk group for proper medication adherence, with non-adherence rates ranging from 50-75%[7]. However, the previously cited study looked at adherence to psychotropic medication, not all medications the patients were prescribed.

Purpose

The purpose of this study was to examine the differences in QOL and medication adherence for PIDD patients with and without concomitant mental health disorders.

Methods

The Immunoglobulin Diagnosis, Evaluation and Key Learnings (IDEaL) Registry is a prospective, observational registry study of patients receiving Ig therapy in the home from one national home infusion company. Following patient consent, data were collected from the SF-36v2 survey administered to patients at baseline and every 6 months during therapy from September 2010 – November 2019. Mental component scores (MCS) and mental health (MH) sub scores were calculated using Optum software[6].

Mental health diagnoses and pertinent mental health medications were obtained from the patient's history and physical (H&P) and medication profile. Patients were placed in three categories: "documented mental health disorder," which were patients with a diagnosed mental health disorder; "mental health medication no diagnosis," which were patients taking a medication that could treat a mental health disorder in the medication profile; but no diagnosis on their H&P and "no mental health disorders," which were patients with no mental health medication nor a diagnosis on their H&P.

Data on medication adherence to Ig therapy were pulled from shipping records for each patient. Each shipment was evaluated to determine if items shipped and the time between shipments matched the prescribed dosage and interval for each patient. These data were then analyzed to find a percentage of correct shipments for each patient.

All data are presented as the mean ± SD, and significance was set at P ≤ 0.05.

Results

Distribution of Mental Health Disorders in Registry Patients

- No Mental Health Disorders — 58.3%
- Mental Health Medication No Diagnosis — 30.1%
- Documented Mental Health Disorder — 11.7%
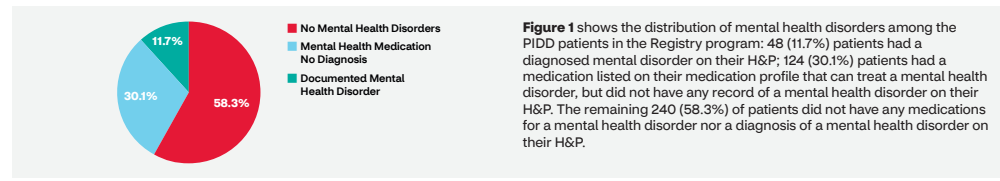
Figure 1 shows the distribution of mental health disorders among the PIDD patients in the Registry program: 48 (11.7%) patients had a diagnosed mental disorder on their H&P; 124 (30.1%) patients had a medication listed on their medication profile that can treat a mental health disorder, but did not have any record of a mental health disorder on their H&P. The remaining 240 (58.3%) of patients did not have any medications for a mental health disorder nor a diagnosis of a mental health disorder on their H&P.

Patients with a Mental Health Disorder Had Significantly Lower MCS on the SF-36v2

- All Patients
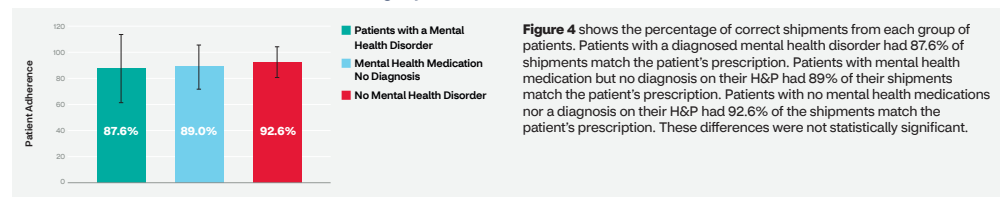- Patients with a Mental Health Disorder
- ** p < 0.01
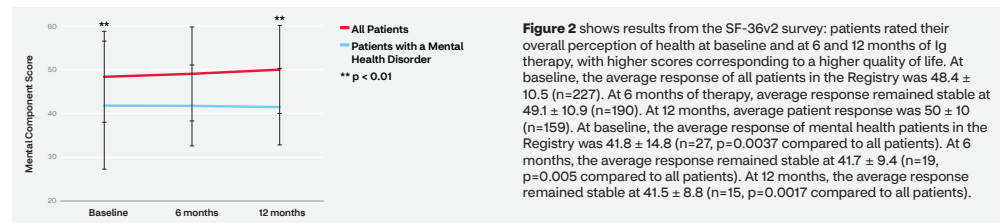
Figure 2 shows results from the SF-36v2 survey: patients rated their overall perception of health at baseline and at 6 and 12 months of Ig therapy, with higher scores corresponding to a higher quality of life. At baseline, the average response of all patients in the Registry was 48.4 ± 10.5 (n=227). At 6 months of therapy, average response remained stable at 49.1 ± 10.9 (n=190). At 12 months, average patient response was 50 ± 10 (n=159). At baseline, the average response of mental health patients in the Registry was 41.8 ± 14.8 (n=27, p=0.0037 compared to all patients). At 6 months, the average response remained stable at 41.7 ± 9.4 (n=19, p=0.005 compared to all patients). At 12 months, the average response remained stable at 41.5 ± 8.8 (n=15, p=0.0017 compared to all patients).

Patients with a Mental Health Disorder Had Significantly Lower MH Sub Scores on the SF-36v2

- All Patients
- Patients with a Mental Health Disorder
- ** p < 0.01
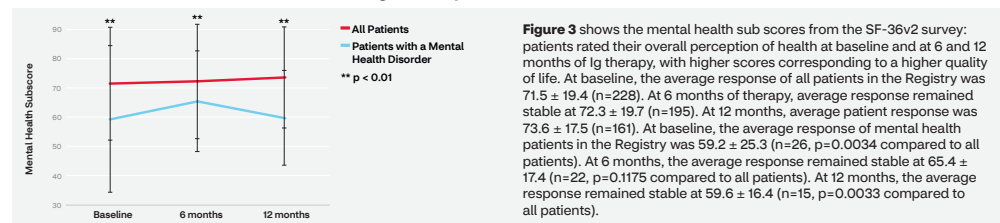
Figure 3 shows the mental health sub scores from the SF-36v2 survey: patients rated their overall perception of health at baseline and at 6 and 12 months of Ig therapy, with higher scores corresponding to a higher quality of life. At baseline, the average response of all patients in the Registry was 71.5 ± 19.4 (n=228). At 6 months of therapy, average response remained stable at 72.3 ± 19.7 (n=195). At 12 months, average patient response was 73.6 ± 17.5 (n=161). At baseline, the average response of mental health patients in the Registry was 59.2 ± 25.3 (n=26, p=0.0034 compared to all patients). At 6 months, the average response remained stable at 65.4 ± 17.4 (n=22, p=0.1175 compared to all patients). At 12 months, the average response remained stable at 59.6 ± 16.4 (n=15, p=0.0033 compared to all patients).

Patients with a Mental Health Disorder Had Slightly Lower Medication Adherence

- Patients with a Mental Health Disorder — 87.6%
- Mental Health Medication No Diagnosis — 89.0%
- No Mental Health Disorder — 92.6%

Figure 4 shows the percentage of correct shipments from each group of patients. Patients with a diagnosed mental health disorder had 87.6% of shipments match the patient's prescription. Patients with mental health medication but no diagnosis on their H&P had 89% of their shipments match the patient's prescription. Patients with no mental health medications nor a diagnosis on their H&P had 92.6% of the shipments match the patient's prescription. These differences were not statistically significant.

Discussion

The prevalence of mental health disorders in our Registry population was twice the national average[1], when combining both medicated and diagnosed patients. As such, when examining QoL in patients with PIDD, researchers should take note of mental health comorbidities prior to analyzing data on mental health QoL.

PIDD patients with mental health disorders had significantly lower MCS and MH scores compared to all Registry patients. This was to be expected due to the impact of mental health disorders on overall and mental health. However, these differences were only noticed when the mental health patients were examined separately from the other subgroups of patients.

Medication adherence was slightly lower in patients with a mental health disorder. Unfortunately, these data were based primarily on shipping records and as a result, one limitation of this study is that the shipments may have been typed incorrectly, which would not be a reflection of patient adherence. These data correspond with other studies showing that patients with mental health disorders have lower medication adherence, even though medication adherence to Ig was higher than reported medication adherence for psychotropic medications[7].

Conclusions

- PIDD patients with concomitant mental health disorders had decreased mental QOL compared to patients without
- PIDD patients with concomitant mental health disorders had slightly lower medication adherence compared to patients without
- Prevalence of mental health disorders was higher than the national average in our PIDD patients

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