

Association of CoVID-19 Omicron BA.1 on adherence to oral tetrabenazine congener and quality of life of patients with Huntington’s Disease with chorea and Tardive Dyskinesia on the service of a USA specialty pharmacy

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BACKGROUND

Patients with complex chronic diseases, e.g., neurologic, cancer, autoimmune, multiple sclerosis and rare diseases, often require specialty drug (SP-D) therapies provided by specialty pharmacies that are: high cost; require special handling by the pharmacy and patients; and require specialty medication therapy management (SPMTM) in order to achieve desirable medication adherence and optimum clinical outcomes. Barriers to achieving desired medication adherence include, but are not limited to, affordability of SP-D, poor patient/family understanding of the disease, psychological status of the patient, which may include forgetfulness or depression, significant and unpleasant side effects of therapy, complicated treatment plans and emergent adverse events and other social determinants of healthcare (SDoHC) access /disparity.^{1,2,3} Social determinants of health that have been shown to greatly and negatively impact medication adherence include social adversities, housing instability, food insecurity, and unemployment.¹⁰ Consequences of nonadherence include: increased health care resource consumption and poor disease treatment outcomes, e.g., increased relapse events, decreased survival time and/or lack of patient/family satisfaction.¹ Specialty pharmacy provided medication therapy management (SPMTM) can be important to achieving acceptable medication adherence and, therefore, better treatment outcomes.^{4,5,6} Coupling SP-D with related SPMTM has been associated with maintaining a medication adherence rate > 0.8 as well a maintaining relatively high level quality of life (QoL) in neurology patients treated with SP-D.^{5, 6, 7}

OBJECTIVE

Two objectives of this study are to determine an association of CoVID-19 OBA.1 pandemic with: (1) Huntington’s Disease with Chorea (HDC) and Tardive Dyskinesia (TDD) patients’ (HDC+TDD) adherence to oral tetrabenazine congener (TBZc) dispensed by a specialty pharmacy (SP) and (2) patient-reported quality of life (QOL) of those patients. The primary objective of the study was to measure the adherence rate to oral TBZc dispensed by the specialty pharmacy. The secondary objective is to compare the QOL of patients who voluntarily participated in the SPMTM program at the program’s Start of Care (SOC) Assessment (before TBXc had been started) and at the Follow-up (F-U) Assessment (after TBZc and SPMTM had been started).

METHODOLOGY

A retrospective, observational, pre-/post (during)-design study of n=280 HDC+TDD SPMTM adherence to oral TBZc and associated QoL was conducted Pre-CoVID-19 OBA.1 (Pre-OBA.1) emergency in the US (4/1-9/30/2020)) and again During-CoVID-19 OBA.1 (During-OBA.1) emergency (1/1-3/31/2022). Patient assessments (PA) occurred at SOC and 7-10 days before refill. PA included EQ-5D-5L QoL, a patient reported outcome (PRO) instrument, which had 5 dimensions with a 5-point Likert scale plus a 0-100 point visual analog scale (VAS100). Dimensions summarized: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Likert scales are summarized: None, Slight, Moderate, Severe, and Extreme plus VAS100 for Overall Health Care Status (0=worst; 100=best possible) . Descriptive statistics were used in both the Pre-OBA.1 and During-OBA.1 data sets to calculate the Pre-OBA.1 dimensional means before and after starting SP-D with SPMTM and then in the F-U in the During-OBA.1 period. The means of the Pre-and During-OBA.1 periods were compared for differences that represented patient perception of improved/no-change/diminished QoL associated with the CoVID-19 OBA.1 emergency. The mean medication possession ratio (MPR), a commonly used medication adherence metric in the USA, was calculated using the F-U from both the Pre- and During-OBA.1 periods. Note: If ≥ 3 therapy-days per month (TxDM) of reported missed/skipped (M/S) SP-D, then pharmacist intervention occurred to determine the reason doses were missed; provide patient re-education/support/encouragement to adhere; and to inform prescriber.

RESULTS

Of the 280 total patients identified, 238 qualified for inclusion in the study (HDC = 94 (39%), TTD = 144 (61%)). The calculated MPR was 0.96 for Pre-OBA.1 and was 0.93 During-OBA.1 (3.1% decrease During-OBA.1). The differences between QoL means Pre- vs During-OBA.1 were: Mobility +0.0081(0.81%), Self-Care +0.002 (0.2%), Usual Activities -0.0022 (0.22%), Pain/Discomfort -0.0103 (0.103%), Anxiety/Depression -0.0089 (0.89%), Over-all Health State -0.07 (0.09%), where “-” difference = improvement/”+”=worsened in Dimensions 1-5; “+” difference = improvement/”-“ difference = worsened in overall health state. Percentages are in absolute values

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CONCLUSION

The During-OBA.1 MPR decreased 3% compared to Pre-OBA.1; however, Pre- and During-OBA.1 MPR were higher than the industry standard of 0.8. On average, across EQ-5D-5L Dimensions, patients reported QoL improved slightly during the During-OBA.1 period compared to that which was reported Pre-OBA.1, except Mobility and Self-care which worsened as did the overall health rating. Explanations associated with the worsened QoL metrics and MPR were possibly associated with continuing challenges to access neurologists, behavioral health providers and pharmacies, protracted social distancing constraints, increased financial hardships and others. Additional studies are suggested to add to the body of evidence characterizing the association of CoVID-19 OBA.1 on SP medication adherence, patient QoL, including SDoHC access/disparities.

Results Table 1
Difference between EQ-5D-5L QoL Means Pre- and During-OBA.1

Dimension	Difference in Means	Interpretation
Mobility....	+0.0081 (0.81%)	Worsened
Self-care	+0.002 (0.2%)	Worsened
U. Daily Activities	-0.0022 (0.22%)	Improved
Pain....	-0.0103 (0.103%)	Improved
Anxiety/Depression	-0.0089 (0.89%)	Improved
Over-all Health	-0.07 (0.09%)	Worsened

Results Table 2
Difference between Adherence (MPR) Pre- and During-OBA.1

Pre-OBA.1	During-OBA.1	Difference	Interpretation
0.96 (96%)	0.93 (93%)	0.031 (3.1%)	Decreased

AUTHORS’ STATEMENTS

Statement of Inclusion:
All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript. Furthermore, each author certifies that this material or similar material has not been and will not be submitted to or published in any other publication.

No Conflict of Interest:
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