Clinical Outcomes in Standard of Care Multiple Sclerosis Treatment: A Case Series

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The purpose of this study was to investigate the effect of use of a special diet on MS symptoms and disease course

Background

- A key question in efforts to reduce symptoms and improve quality of life (QoL) for multiple sclerosis (MS) patients is whether using a therapeutic lifestyle (diet, stress reduction and exercise) as part of a treatment and wellness plan is associated with:
  - Reduced MS-related symptoms
  - Reduced rate of documented relapse rate
  - Favorable changes in brain imaging studies
- Previous work from Dr. Wahls' lab suggests that a modified Paleolithic diet significantly reduces MS-related fatigue and improves QoL[1,2]
  - This group has recently completed a randomized control trial comparing the modified Paleolithic diet to the low-saturated fat diet developed by Dr. Swank[3]
- There is growing evidence from Dr. Wahls' group and others that a therapeutic diet and lifestyle may benefit MS patients.[4-9]
- Review of current practices in MS care at University of Iowa Hospitals & Clinics (UIHC) will aid in better understanding trends in MS symptoms and disease progression

Materials and Methods

- A list of medical records was generated for all newly diagnosed UIHC Neurology patients with clinically isolated syndrome (CIS) or relapsing-remitting MS (RRMS) from 1/1/2018 to 12/31/2020, yielding 2,500 patients
- Patients were randomly selected and screened for eligibility
  - Inclusion criteria: age 18-55 years, longitudinal MS care at UIHC
- All MS-relevant progress notes, laboratory results and radiology studies were abstracted to collect the following data:
  - Use of a special diet
  - Current MS symptoms
  - Functional impairments (e.g., vision, walking, hand, pain, bladder, bowel) over time
- Clinical course was evaluated by:
  - Assessing documented change (improved, stable or worsened) in functional impairments as well as documented relapses
  - Change (increased, stable, decreased) in number and size of enhancing lesions on magnetic resonance imaging (MRI) of the brain, cervical spine and thoracic spine
  - Changes in disease-modifying drug treatments (DMT) (i.e., escalating from oral to injection to infusion)
- All data was retrospectively collected from participant EPIC charts and recorded in REDCap forms with omitted PHI to maintain privacy

Results

Demographics		
Sex		
N = 40	**Freq**	**Percent**
Female	30	75
Male	10	25
Age		
Mean	**Std Dev**	**Range**
36.9	8.8	18 - 51
Race		
	Freq	**Percent**
African-American/Black	1	2.5
Asian	1	2.5
Declined	1	2.5
Hispanic/Latino of any race	2	5
Multiracial/Two or More Races	1	2.5
White	34	85

Participants Utilizing a Special Diet: 5 (12.5%)	
Diet	**Freq**
Wahls	1
Low red meat	1
Low cholesterol	1
Intermittent Fasting 18/6	1
AIP (no dairy, sugar, gluten)	1

*All 5 participants utilized a DMT in conjunction with their diet

Participants Utilizing a DMT: 36 (90%)	
DMT	**Freq (%)**
Ocrevus (Infusion)	21 (52.5)
Copaxone (Injection)	10 (25)
Tecfidera (Oral)	8 (20)
Vumerity (Oral)	4 (10)
Ofatumamab (Injection)	2 (5.0)
Plegridy (Injection)	2 (5.0)
Betaseron (Injection)	1 (2.5)
Rebif (Injection)	1 (2.5)
Aubagio (Oral)	1 (2.5)

Imaging trends	
Participants with more than 1 MRI: 35 (87.5%)	**Freq (%)**
Radiologic improvement	5 (12.5)
Stable lesions	23 (57.5)
Radiologic worsening	7 (17.5)

Table of change from one DMT to another				
Initial DMT	**Second DMT**			
	Rebif	**Ocrevus**	**Ofatumamab**	**Vumerity**
Betaseron	0	1	0	0
Copaxone	0	6	0	0
Tecfidera	1	1	1	1
Aubagio	0	0	0	1
Plegridy	0	1	0	1

***10 (25%) patients had an escalation of their DMT**

Average progress notes per participant	Average span of data collection (days)	Average MS relapses per participant
5.7 ± 2.8	484 ± 273 (range: 36 - 1054)	1.2 ± 1.1

Summary of a single participant (Sex: Female, Age: 51)

Medical Record Information						MRI Information					
Record Count	Months	MS Status	Relapse	Medication	Diet	Record count	Brain	Cervical	Thoracic	Lesions	Status
	0					1	Yes	No	No	enhancing	
	0.1					2	No	Yes	Yes	non-enhancing	
1	0.1	Worsened	Yes	not mentioned	No						
2	1.3	Improved	No	injection[A]	No						
3	1.5	Stable	No	injection	No						
4	2.2	Improved	No	injection	No	3	Yes	No	No	non-enhancing	stable
5	3.7	Stable	No	injection	No						
6	4.6	Worsened	Yes	injection	No						
7	5	Worsened	Yes	injection	No						
8	5	Stable	Yes	injection	No						
	5.1					4	Yes	No	No	non-enhancing	stable
9	5.8	Stable	No	infusion[B]	No						
10	7.3	Stable	No	infusion	No						
11	10.4	Stable	No	infusion	No						
12	10.7	Stable	No	infusion	No						
13	11.1	Stable	No	infusion	No						
14	11.6	Stable	No	infusion	No						
15	16	Stable	No	not mentioned	No						
16	16.5	Stable	No	infusion	No	5	Yes	No	No	non-enhancing	stable
17	16.5	Stable	No	infusion	No	6	No	Yes	No	non-enhancing	stable
	18					7	Yes	No	No	non-enhancing	stable
18	20.7	Stable	No	infusion	No						

[A] Copaxone

[B] Ocrevus

Conclusions

Overall, descriptive statistics provide a better understanding of the disease progression for patients being treated at UIHC. Procedures for chart abstraction, definition of terms and data analyses will be refined in close collaboration with the study biostatistician to establish the effect size of utilizing a special diet on clinical course as defined by change in functional impairments, overall MS symptoms and size and number of documented MRI lesions. Future work will also involve comparison of this study population with a prospective nationwide standard-of-care arm and an interventional arm for a currently ongoing Health Behaviors clinical trial (IRB #: 201908778).

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