

Introduction

- Microscopic colitis is an increasingly recognized inflammatory condition and is a frequent cause of chronic diarrhea in the developed world. Current treatments for microscopic colitis (MC) are antidiarrheals, budesonide, and avoidance of exacerbating medications^{1,2}.
- There is currently no formal treatment guideline for the use of biologic medications in patients who continue to have severe symptoms after use of first line treatment options (20%)^{3,4}.
- **Objective:** To analyze the clinical use, safety profile, and efficacy of biologic medications in refractory microscopic colitis.

Methods and Materials

- Patients at a large academic center in Boston, MA with an ICD-10 diagnosis of collagenous colitis or lymphocytic colitis. These patients were further narrowed to those who had trialed infliximab, adalimumab, vedolizumab, or ustekinumab
- Each patient chart was individually reviewed by two authors (RA, LB), with conflicting charts reviewed by a gastroenterologist (JDF).
- Data regarding date of diagnosis, histologic phenotype, demographics, concomitant GI illness, medications prior to biologic use, biologics trialed, length of treatment, adverse events, and clinical outcomes were analyzed descriptively.

Characteristics	Data (n = 12)
Race	
White	100 % (12/12)
Gender	
Male	33.3% (4/12)
Female	66.7% (8/12)
Diagnosis	
Collagenous Colitis	50% (6/12)
Lymphocytic Colitis	41% (5/12)
Microscopic Colitis NOS	9% (1/12)
Concomitant GI Illness	50% (6/12)
IBD	25% (3/12)
Celiac Sprue	25% (3/12)
Age at Diagnosis (years)	57 ± 12
Charlson Comorbidity Index	2.3 ± 1.4
Medications Prior to Biologic	
Steroids	92% (11/12)
Prednisone	27% (3/12)
Budesonide	72% (8/11)
Anti-Diarrheals	100% (12/12)
5-ASA	42% (5/12)
Length of Disease Prior to Biologic (years)	1.7 +/- 1.6
Length of Biologic Treatment (years)	3.7 +/- 3.3

Table 1. Summary data regarding patients with Microscopic Colitis treated with biologics.

Results

- A total of 1947 patients were identified with a diagnosis of MC. Of those, 98 (5%) patients had been exposed to biologics, and only 12 (< 1%) total patients were started on a biologic medication primarily for MC.
- Average length of diagnosis prior to biologic was 1.7 +/- 1.6 years.
- Average length of biologic treatment was 3.7 +/- 3.3 years, with eight patients continuing medication currently.
- Four patients achieved clinical remission and four switched biologic class or medication due to medication non-effectiveness.

Outcomes	Data
Clinical Remission	
6 weeks	45% (5/11)*
6 months	45% (5/11)*
Histologic Remission	0% (0/9)*
Adverse Events	16% (2/12)
	Ustekinumab associated with an anaphylactic like allergic reaction two years after initiating therapy
	Infliximab associated with a pelvic abscess 6.7 years after initiating therapy.

Table 2. Outcomes of patients with Microscopic Colitis treated with biologics. *Data was not available for all patients

Discussion

- Only a very small percentage of patients diagnosed with MC were initiated on biologic treatment for directed therapy at a large academic institution.
- Some patients on biologic therapy achieved clinical remission, suggesting medical benefit to some patients in this population.
- Overall safety seemed to be well tolerated with longer term follow up.
- Until now only a handful of series/cohorts have been described with patients with microscopic colitis. Our results are consistent with a recently published meta-analysis showing 54% of patients at 3-4 months were in clinical remission⁵.
- Study is limited by retrospective nature, limited number, as well as provider variability in prescribing.

Conclusions

- Overall, MC has a low incidence and few patients are prescribed biologics for treatment. There is a need for further research to establish guidelines for use of biologics in treatment.
- In a small subset of patients, there seemed to be success with minimal adverse events.

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