Use of Newer Biologic Therapies in Patients with Refractory Microscopic Colitis

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ABSTRACT

BACKGROUND

Several treatment options exist for microscopic colitis (MC), with the most common being budesonide. While budesonide results in response or remission in most patients, some patients do not respond, have side effects, or need long term maintenance. Biologics including anti-tumor necrosis factor alpha (TNF-a) have been described for MC, but vedolizumab and ustekinumab use has been uncommonly reported. We aimed to assess the effectiveness and safety of these newer biologics in patients with MC.

METHODS

Patients seen at an academic referral center were identified from the medical record using diagnostic codes for microscopic, lymphocytic, or collagenous colitis who were prescribed a biologic treatment. Diagnoses and use of biologic therapy were confirmed by chart review. We selected patients who received at least one dose of vedolizumab or ustekinumab. Response was defined as complete response (resolution of diarrhea), partial response (at least 50% improvement but not resolution), nonresponse (<50% improvement), or intolerance (drug stopped due to adverse event).

RESULTS

Sixteen patients were identified. Three patients were lost to follow-up leaving thirteen in this study cohort (12 received vedolizumab and 1 ustekinumab). The median age at start of biologic therapy was 47 years (range 33-76) and 69% were female. Most patients (76.9%) were budesonide refractory and four had failed anti TNF-a therapy.

In the vedolizumab group, two (16.7%) achieved complete response, five had partial response (41.7%), and five (41.7%) were non-responders. Two out of 5 with partial response lost response; 1 responded to dose escalation and 1 (who could not stop NSAID use) did not. Two patients (16.7%) reported vomiting and nausea following vedolizumab infusions, but no patient had to discontinue receiving treatment due to adverse events. The one ustekinumab treated patient had partial response to every 8-week dosing and achieved complete response with escalation to every 4-week dosing.

CONCLUSIONS

Vedolizumab and ustekinumab may be viable options for refractory MC, including in patients who did not respond to anti TNF-a therapy, although dose escalation may be needed. Complete remission with vedolizumab was lower than has been reported previously. Prospective, randomized, controlled trials of these newer agents are needed to define their role in the treatment algorithm for patients with MC.

OBJECTIVES

- We aimed to evaluate the efficacy and safety of vedolizumab and ustekinumab in patients with refractory microscopic colitis.

METHODS

- Patients with diagnostic codes for microscopic, lymphocytic, or collagenous colitis who were prescribed a biologic of interest were identified.
- Retrospective chart review was conducted.
- Response to biologic indicated as:
  - Complete response (CR) (resolution of diarrhea)
  - Partial Response (≥ 50% improvement without resolution)
  - Nonresponse (<50% improvement)
  - Intolerance (treatment stopped due to adverse event)

RESULTS

- Sixteen patients were identified, 3 were lost to follow up.
- Median age at start of treatment was 47 years.
- 12 patients received vedolizumab.
- 1 patient received ustekinumab.

RESULTS

Study Population Demographics

Age (Range, Median)	Gender (M, F)	Failed Anti TNF-a therapy	Previous Budesonide	Biologic Used (Vedolizumab, Ustekinumab)
33-76, 47	4 (31%), 9 (69%)	4 (31%)	10 (76.9%)	12 (92%) , 1 (8%)

Table 1: Baseline characteristics in study population

- Vedolizumab cohort:
  - Two (16.7%) achieved complete response
  - Five (41.7%) achieved partial response
    - One achieved complete response with dose escalation
    - Two lost response
  - Five (41.7%) were non-responders
  - Two patients reported nausea and vomiting post infusion
  - No discontinuation due to adverse events
- Ustekinumab patient achieved complete response with dose escalation to every 4 weeks dosing

Treatment Outcomes

	Vedolizumab	Ustekinumab
Complete response	2	0
Partial response	5	1
Nonresponse	5	0
Intolerance	0	0
Total	12	1

Table 2: Results following treatment for respective biologic treatment

CONCLUSIONS

- Vedolizumab and ustekinumab may be viable options for refractory microscopic colitis, including patients who did not respond to anti TNF-a therapy.
- Complete response rate was lower than previously reported for vedolizumab.
- Dose escalation of the newer biologics in MC might be useful for achieving complete response.
- Further research is needed to evaluate the efficacy and safety of vedolizumab and ustekinumab.

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