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Pharmacological Management of Adult Outpatients With Moderate to Severely Active Ulcerative Colitis

Clinical Decision Support Tool

Adult outpatients with moderate to severely active ulcerative colitis

Moderate to severely active UC, defined as:

- Patients deemed to be at high-risk for colectomy
- Mayo Clinic Score 6–12, with Mayo Endoscopic Subscore 2 or 3
- Severely active endoscopic disease, with ulcers
- Patients with corticosteroid dependence, or refractory to oral corticosteroids

Suggest using biologic agents (with or without immunomodulators) EARLY, rather than gradual step-up after failure of 5-aminosalicylate therapy
(conditional recommendation, very low quality of evidence)

Comment: patients, particularly those with less severe disease, who place higher value on the safety of 5-aminosalicylate therapy, and lower value on the efficacy of biologic agents or tofacitinib, may reasonably choose gradual step therapy with 5-ASA therapy

Biologic therapy and tofacitinib

Recommend choosing any of the following, over no treatment: infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, ustekinumab
(strong recommendation, moderate quality of evidence)

Biologic-naïve patients; first-line therapy

First-line therapy

Suggest using infliximab or vedolizumab, rather than adalimumab
(conditional recommendation, moderate quality of evidence)

Comment: patients, particularly those with less severe disease, who place higher value on the convenience of self-administered subcutaneous injection, and a lower value on the relative efficacy of medications, may reasonably choose adalimumab as an alternative

Recommend tofacitinib* use in biologic-naïve patients only in setting of clinical or registry study
(no recommendation, knowledge gap)

Comment: updated FDA recommendations (07/26/2019) on indications for use of tofacitinib in ulcerative colitis recommends its use only after failure of, or intolerance of, TNFα antagonists

Prior failure of infliximab, particularly primary non-response

Second-line therapy

Suggest using ustekinumab or tofacitinib*, rather than vedolizumab or adalimumab
(conditional recommendation, very low quality of evidence)

Comment: Patients, particularly those with less severe disease, who place higher value on the potential safety of medications, and a lower value on the relative efficacy, may reasonably chose vedolizumab as an alternative

In adult outpatients with moderate to severely active ulcerative colitis who have achieved remission with biologic agents and/or immunomodulators or tofacitinib, suggest against continuing 5-aminosalicylates for inducing and maintaining remission
(conditional recommendation, very low quality evidence)

Thiopurines and methotrexate

Suggest combining infliximab, adalimumab, golimumab, vedolizumab, or ustekinumab with thiopurines or methotrexate, rather than using biologic monotherapy or thiopurine monotherapy
(conditional recommendation, low quality of evidence)

Comment: patients, particularly those with less severe disease, who place higher value on the safety of biologic monotherapy, and lower value on the efficacy of combination therapy, may reasonably choose biologic monotherapy

Suggest AGAINST using thiopurine monotherapy for *inducing remission* in patients with active disease
(conditional recommendation, very low quality of evidence)

Suggest using thiopurine monotherapy, rather than no treatment, for *maintaining remission* in patients with quiescent disease
(conditional recommendation, low quality of evidence)

Suggest AGAINST using methotrexate monotherapy for *inducing or maintaining remission*
(conditional recommendation, low quality of evidence)

Suggest using biologic monotherapy or tofacitinib, rather than thiopurine monotherapy for inducing remission in patients with active disease
(conditional recommendation, low quality of evidence)

No recommendation in favor of, or against, using biologic monotherapy or tofacitinib, rather than thiopurine monotherapy for maintaining remission in patients with quiescent disease
(conditional recommendation, low quality of evidence)

*Tofacitinib dose = 10mg BID for 8 weeks for induction, followed by 5mg BID for maintenance

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Pharmacological Management of Adult Patients Hospitalized With Acute Severe Ulcerative Colitis

Clinical Decision Support Tool

Adults hospitalized with acute severe ulcerative colitis

Acute severe ulcerative colitis defined based on Truelove and Witts criteria as ≥ 6 bloody bowel movements/day with at least one marker of systemic toxicity including:

- **Heart rate > 90 beats/minute**
- **Temperature > 37.8C**
- **Hemoglobin < 10.5 g/dL**
- **Erythrocyte sedimentation rate > 30 mm/h**

Suggest using intravenous methylprednisolone dose equivalent 40–60mg/d, rather than higher doses of corticosteroids
(conditional recommendation, very low quality of evidence)

Suggest AGAINST using antibiotics as adjunct therapy in the absence of infections
(conditional recommendation, very low quality of evidence)

Patients refractory to trial of intravenous corticosteroids *(trial of intravenous corticosteroids is suggested for 3–5 days, with limited benefit of trial extending for > 7 days)*

Suggest using infliximab or cyclosporine to avoid short-term risk of colectomy
(conditional recommendation, very low quality of evidence)

No recommendation in favor of, or against, routine use of intensive (higher dose and/or shortened interval) infliximab dosing regimens, rather than standard infliximab dosing regimens
(no recommendation, knowledge gap)