# Drug Therapy 2021
# "IBD: New Treatment Paradigms"

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## Faculty/Presenter Disclosure

- **Waqqas Afif**

Relationships with Commercial Interests:

- Grant/Research Support: Abbvie, Janssen, Pfizer, Takeda
- Advisory Boards/Honoraria: Abbvie, Amgen, Arena Pharmaceuticals, Dynacare, Fresnius-Kabi, Janssen, Merck, Novartis, Pfizer, Sandoz, Takeda.

# LEARNING OBJECTIVES

1. **Describe the treatment goals and medications used to achieve these goals in patients with IBD**
2. **Understand the utility of biosimilar medications in patients with IBD**
3. **Provide IBD chronic disease co-management in a planned and proactive manner**

# CANMEDS Roles

| | |
|---|---|
| X | **Medical Expert** (as *Medical Experts*, physicians integrate all of the CanMEDS Roles, applying medical knowledge, clinical skills, and professional values in their provision of high-quality and safe patient-centered care. *Medical Expert* is the central physician Role in the CanMEDS Framework and defines the physician's clinical scope of practice.) |
| | **Communicator** (as *Communicators*, physicians form relationships with patients and their families that facilitate the gathering and sharing of essential information for effective health care.) |
| X | **Collaborator** (as *Collaborators*, physicians work effectively with other health care professionals to provide safe, high-quality, patient-centred care.) |
| X | **Leader** (as *Leaders*, physicians engage with others to contribute to a vision of a high-quality health care system and take responsibility for the delivery of excellent patient care through their activities as clinicians, administrators, scholars, or teachers.) |
| | **Health Advocate** (as *Health Advocates*, physicians contribute their expertise and influence as they work with communities or patient populations to improve health. They work with those they serve to determine and understand needs, speak on behalf of others when required, and support the mobilization of resources to effect change.) |
| X | **Scholar** (as *Scholars*, physicians demonstrate a lifelong commitment to excellence in practice through continuous learning and by teaching others, evaluating evidence, and contributing to scholarship.) |
| | **Professional** (as *Professionals*, physicians are committed to the health and well-being of individual patients and society through ethical practice, high personal standards of behaviour, accountability to the profession and society, physician-led regulation, and maintenance of personal health.) |

# IBD: Diagnosis

## Red flag questionnaire for IBD CD & UC

(1) Nonhealing or complex perianal fistula or abscess or perianal lesions (apart from hemorrhoids)

(2) First-degree relative with confirmed IBD

(3) Weight loss (5% of usual body weight) in the last 3 months

(4) Chronic abdominal pain (>3 months)

(5) Nocturnal diarrhea

(6) Mild fever in the last 3 months

(7) No abdominal pain 30–45 min after meals, predominantly after vegetables

(8) No rectal urgency *(Reversed from 'presence of rectal urgency' to obtain a positive rounded coefficient)*

IBD, inflammatory bowl disease.

1. Danese S et al. J Crohns Colitis. 2015;9(8):601-606; 2. Fiorino G et al. J Crohns Colitis. 2020;14(12):1777-1779.

# Fecal calprotectin as a screen for IBD

- Protein released by white blood cells
- Indicative of inflammation within the bowel
- Can help distinguish IBD from IBS

- Primary care FC testing can avoid unnecessary invasive investigations and reduce time from diagnosis to treatment[1]
- FC test has extremely high negative predictive value - therefore inflammation of the bowel is unlikely if a negative result[2]
  - Negative result = useful reassurance that no concurrent bowel inflammation in patients less likely to have IBD

FC, fecal calprotectin; IBD, inflammatory bowel disease; IBS, irritable bowel syndrome.
1. Hicks A et al. Inflamm Intest Dis. 2020;5(4):191-199; 2. McDonald BS. Clin Exp Dermatol. 2021;46(3):573-574.

# Biomarkers for Detection of Endoscopic Activity in Symptomatic IBD Patients

**DIAGNOSTIC ACCURACY OF FECAL CALPROTECTIN, STOOL LACTOFERRIN, AND C-REACTIVE PROTEIN FOR ENDOSCOPICALLY ACTIVE DISEASE**

| Marker | Sensitivity | Specificity | Positive LR | Negative LR | AUC | Diagnostic OR |
|---|---|---|---|---|---|---|
| **C-reactive protein** | | | | | | |
| **Fecal calprotectin** | | | | | | |
| IBD | 0.88 (0.84, 0.90) | 0.73 (0.66, 0.79) | 3.2 (2.6, 4.1) | 0.17 (0.14, 0.21) | 0.89 (0.86, 0.91) | 19 (13, 27) |
| UC | 0.88 (0.84, 0.92) | 0.79 (0.68, 0.87) | 4.2 (2.8, 6.4) | 0.15 (0.11, 0.20) | 0.91 (0.89, 0.94) | 28 (18, 46) |
| Sensitivity analysis 1[a] | 0.87 (0.82, 0.90) | 0.71 (0.62, 0.78) | 3 (2.3, 3.8) | 0.19 (0.14, 0.24) | 0.87 (0.84, 0.90) | 16 (11, 23) |
| Sensitivity analysis 2[a] | 0.87 (0.83, 0.91) | 0.71 (0.63, 0.78) | 3 (2.3, 3.9) | 0.18 (0.13, 0.24) | 0.88 (0.85, 0.91) | 19 (14, 28) |
| Sensitivity analysis 3[a] | 0.88 (0.84, 0.91) | 0.73 (0.66, 0.79) | 3.2 (2.5, 4.1) | 0.17 (0.13, 0.21) | 0.89 (0.86, 0.92) | 19 (14, 28) |
| Sensitivity analysis 4[a] | 0.87 (0.83, 0.90) | 0.72 (0.65, 0.78) | 3.2 (2.5, 3.9) | 3.1 (2.5, 3.9) | 0.88 (0.85, 0.91) | 17 (12, 24) |
| **Stool lactoferrin** | | | | | | |
| IBD | 0.82 (0.73, 0.88) | 0.79 (0.62, 0.89) | 3.8 (2.0, 7.5) | 0.23 (0.14, 0.38) | 0.87 (0.84, 0.90) | 16 (6, 48) |

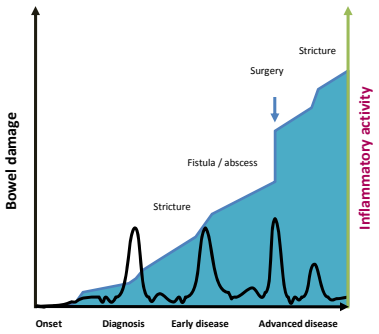
AUC, area under the curve; CD, Crohn's disease; IBD, inflammatory bowel disease; LR, likelyhood ratio; OR, odds ratio; UC, ulcerative colitis.
aSensitivity analysis 1: excluding studies that included healthy controls that did not undergo colonoscopy; sensitivity analysis 2: excluding studies that included any patient not known to have a diagnosis of inflammatory bowel disease; sensitivity analysis 3: excluding one study that examined patients presenting with lower gastrointestinal symptoms; and sensitivity analysis 4: excluding two studies that were published in abstract form.
Mosli, MH et al. *Am J Gastroenterol* 2015; 110(6): 802-19.

# Treatment Targets in IBD

# Progressive nature of IBD

**CD and UC are chronic progressive conditions, with a major clinical and patient burden.**

**THEORETICAL PATIENT WITH CROHN'S DISEASE[1]**




**CLINICAL EVIDENCE IN CROHN'S DISEASE**

**Bowel damage increases over time in many CD patients**

- Over median 23 months, bowel damage increased in >1/3 of patients[2]
- Over 5 years, bowel damage increased in 48% of patients[3]
- At 2–10 years post diagnosis, >50% had substantial damage[4]

1. Pariente B, et al. *Inflamm Bowel Dis* 2011;17:1415–22; 2. *Duveau N*, et al. *J Crohns Colitis* 2015; 9(Suppl1):S57;
3. *Bhagya Rau B*, et al. *J Clin Gastroenterol* 2016;50:476-82; 4. *Giletta C*, et al. *Clin Gastroenterol Hepatol* 2015;13:633-40

# Treat-to-Target recommendations (IBD)

**COMPOSITE ENDPOINT**

**CLINICAL / PRO REMISSION**

**Defined as resolution of abdominal pain and normalisation of bowel habit**

- Assessed at minimum of 3 months during active disease
- Patients' individual goals should also be addressed

**AND**

**ENDOSCOPIC REMISSION**

**Defined as resolution of ulceration**

- Should be assessed within 6–9 months after start of therapy
- When endoscopy cannot adequately evaluate inflammation, assess resolution of inflammation by cross-sectional imaging

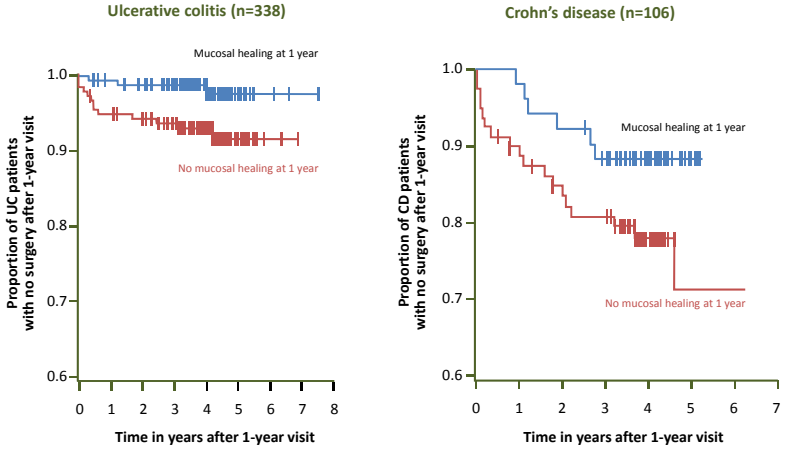
**ADJUNCTIVE MEASURES**

- **Biomarkers:** CRP and faecal calprotectin are adjunctive measures of inflammation, not targets, for monitoring CD
- **Histology:** histologic remission is not considered a target

Peyrin-Biroulet L, *et al. Am J Gastroenterol* 2015;110:1324–38

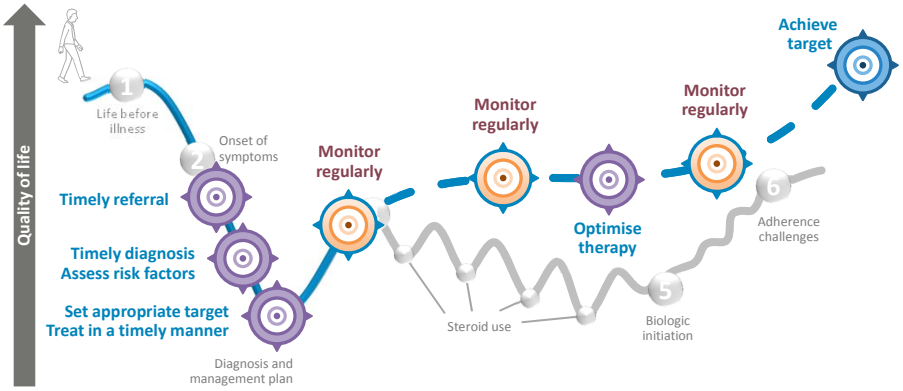
# Importance of mucosal healing for long-term outcomes in IBD: IBSEN cohort

## Mucosal healing status at 1 year and risk of surgery



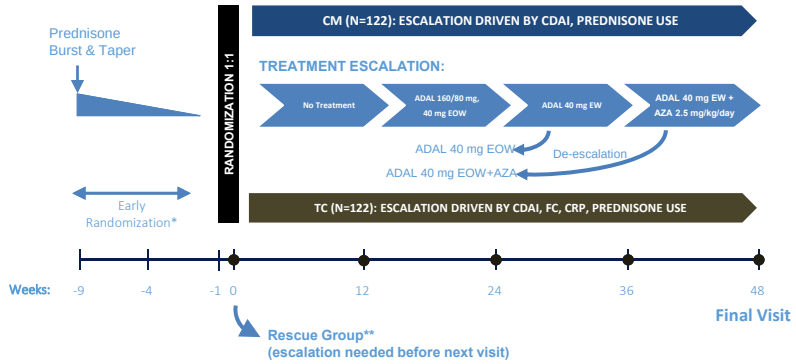

Froslie KS, *et al. Gastroenterology* 2007;133:412–22.

# Regular monitoring of objective markers informs treatment optimisation



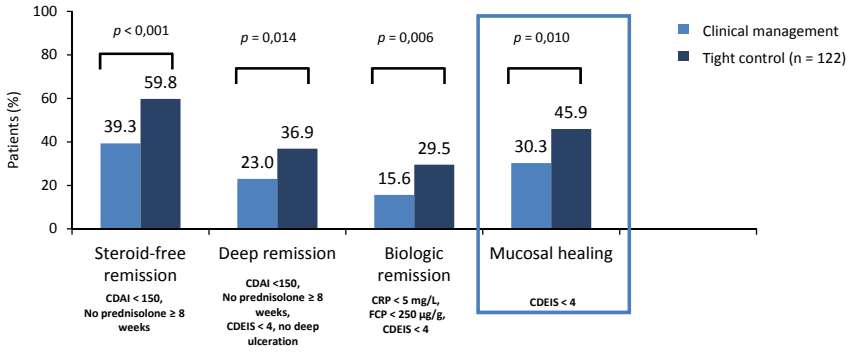

Change in quality of life in a theoretical IBD patient

# **CALM**: Effect of tight control using fecal calprotectin Study design




ADAL=Adalimumab, CM=clinical management, TC= tight control, EW=every week, EOW = every other week, AZA= azathioprine
*CDAI>220 AND one of the following: steroid therapy > 4 weeks and best to taper per investigator assessment, intolerant/contraindication for steroid therapy, best interest of the patient per investigator assessment.
** CDAI > 300 for 2 consecutive visits 7 days apart or per investigator discretion (elevated CRP/FC, ulceration taken into consideration); moved to TC group.
Colombel J-F et al. *Lancet* 2017 [epub ahead of print]

# What do the results of close monitoring look like?




CDAI, *Crohn's Disease*; CDEIS, *Crohn's Disease Endoscopic Index of Severity*; CRP, C-reactive protein; FCP, FC: faecal calprotectin;
Colombel JF, et al. Lancet 2017.
Colombel JF, et al. Présenté lors de la Digestive Disease Week, du 6 au 9 mai 2017, Chicago, Illinois; résumé 718.

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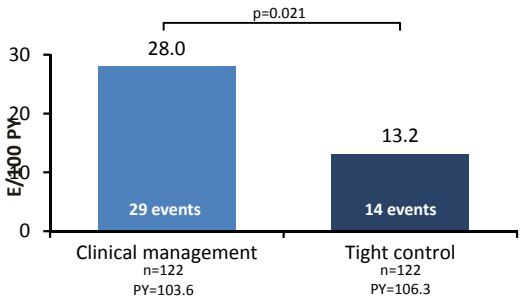
# CALM: Post hoc Analysis




**Study design:** Post hoc analysis of CALM that assessed the rates of CD-related hospitalizations after randomization to tight control or clinical management strategies with adalimumab

**Key results:**

- The tight control approach with adalimumab was associated with significantly fewer events of CD-related hospitalization than the clinical management group

E=Events; PY=Patient Years
Colombel J-F et al. UEGW 2017 OP 227

# IBD Treatment

## Canadian Association of Gastroenterology: Clinical Practice Guideline for the Management of Luminal Crohn's Disease

**Statement 1. Recommendation: determination of disease severity be based on:**


**Table 1. Factors Associated With High Risk of Relapse, Surgery, or Complicated Luminal CD**

| Clinical factors | Laboratory factors | Disease factors | Endoscopic factors |
|---|---|---|---|
| Younger age | Low hemoglobin | Disease location (rectal, upper GI, jejunal) | Presence of deep ulceration |
| Smoking | Low albumin | Disease extent | |
| Longer disease duration | High C-reactive protein (CRP) | | |
| Early use of corticosteroids | High faecal calprotectin levels | | |
| Presence of fistulizing perianal CD | | | |
| Previous intestinal resection | | | |

Panaccione R. and al. JCAG 2019; 2(3): e1–34

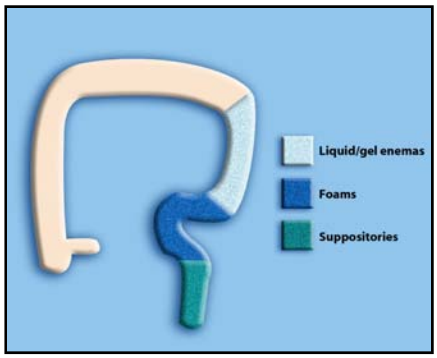
## IBD Treatment: Induction/Maintenance

- 5-ASA's
  - UC only for **induction & maintenance** → works in 70% of UC patients
- Corticosteroids
  - CD/UC for **induction only**
  - Prednisone & budesonide
- Immunomodulators
  - Methotrexate (MTX)
    - CD for **induction & maintenance**
  - Thiopurines
    - CD for **maintenance only**
- Biologic medications/small molecules
  - For **induction and maintenance** (+/-thiopurine/MTX)
    - Anti-TNF: infliximab/adalimumab (UC/CD), golimumab (UC)
    - α4-β7: vedolizumab (UC/CD)
    - IL 12/23: ustekinumb (UC/CD)
    - JAKi: tofacitinib (UC)

## Mild to Moderate Active UC

# Treatment of Active Ulcerative Colitis

- 5-ASA suppositories (1g qhs)
- 5-ASAs enemas (2g/4g qhs)
- Oral 5-ASA for disease extending past the splenic flexure (or combo with rectal)
- Corticosteroid foam/enema
- If no help, consider oral budesonide MMX (Cortement)




**Proximal distribution of topical preparations**

Adapted from: Marshall JK, Irvine EJ. *Am J Gastroenterol* 2000; 95: 1628-1636.

## 5-Aminosalicyates vs. Sulfasalazine Toxicity

**Only sulfa-related**
- Male infertility
- Hemolytic anemia
- Agranulocytosis

**Both Sulfa and 5-ASA**
- Alveolitis
- Pancreatitis

**5-ASA**
- Nephritis

**Sulfa 》5-ASA**
- Rash
- Fever
- Headache
- Nausea
- Dyspepsia
- Neutropenia
- Hepatitis

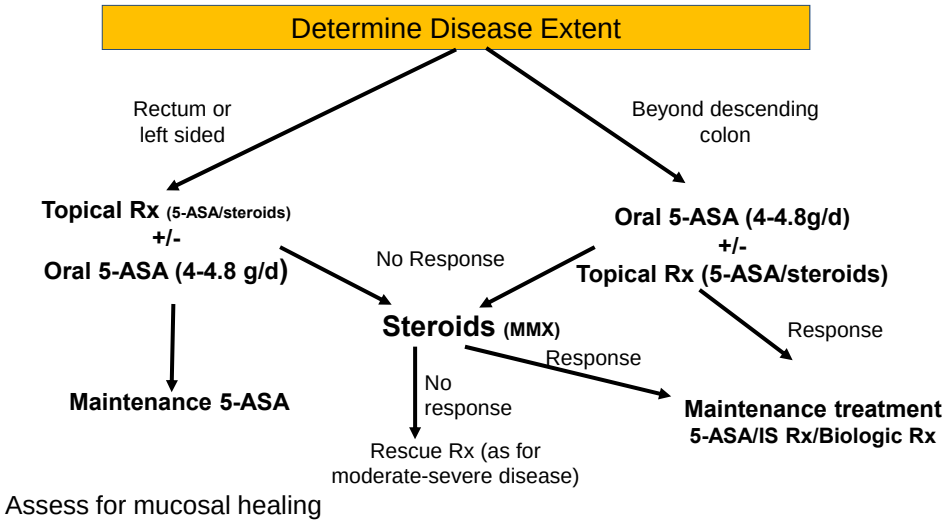
Courtesy of the AGA (Teaching Slides)

# What can you do in the clinic in the patient with a flare of symptoms

Rule out infectious cause → stool C/S and C. *difficile*

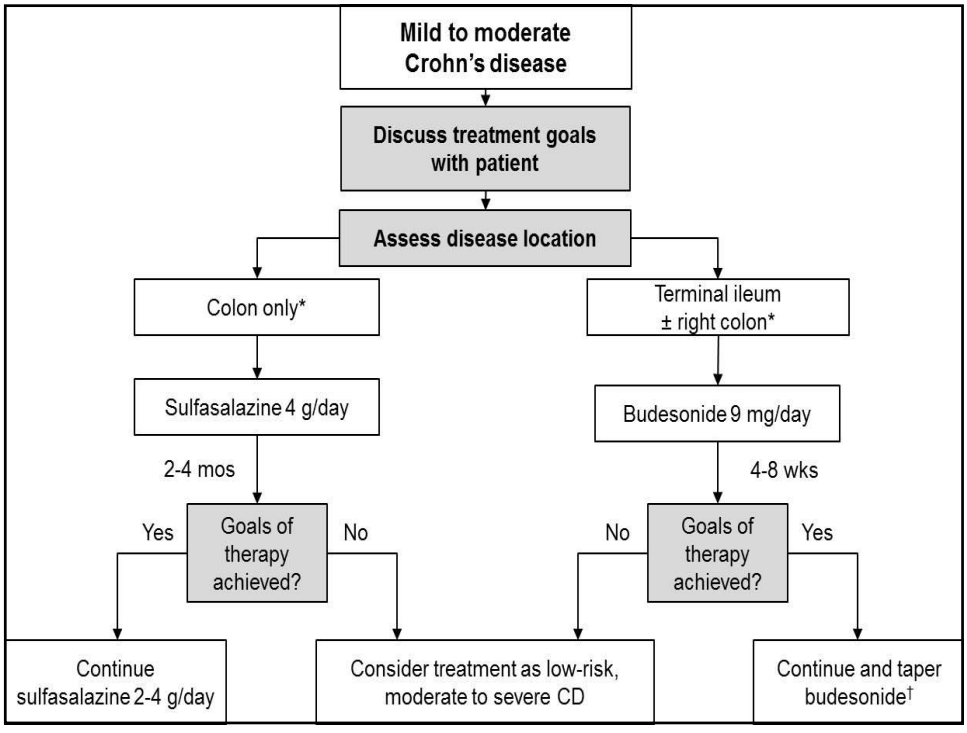
*Get CRP/FCP*

## Management of Active UC- Algorithm Mild to Moderate




Assess for mucosal healing

# Mild Crohn's Disease

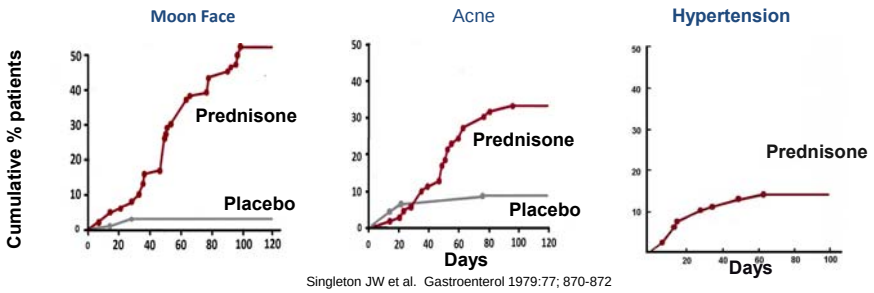


## Oral Corticosteroids for IBD
## Failure of 5-ASA/Cortement/Entocort

- Oral prednisone 40-60 mg/day is effective for inducing remission in moderate to severely active IBD in controlled trials
- Oral prednisone is **NOT** effective for maintenance of remission in controlled trials

Kornbluth et al., ACG March 2010, 105 (3); 501-523.

## Corticosteroid side effects




Singleton JW et al. Gastroenterol 1979:77; 870-872

**Bone disease** : Osteopenia/porosis → duration, dose dependent
Osteonecrosis → high dose, prolonged tx, 0.5-4.3%

**Endocrine**: HPA suppression, diabetes

**Ocular:** Glaucoma, cataracts → duration, dose dependent

**Neuropsychological issues**

**Infection risks & increased risk of mortality**

# Clinical Pearls: Corticosteroids

- Patient should have significant improvement of symptoms prior to tapering (1-2 weeks)
- If patient does not respond, need to consider alternative treatment
- Taper slowly (5 mg/week). If recurrent symptoms, increase dose and consider alternative treatment
- CS are a bridge to another treatment
  - Can not be used to maintain remission

## AGA & CAG Guidelines:

Induction of remission (moderate to severe)

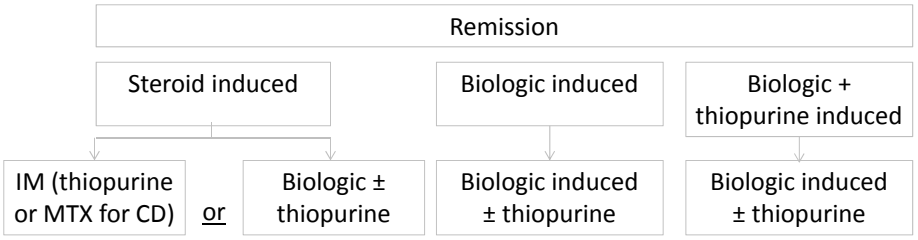
**Moderately severe IBD <u>despite</u> standard therapies**
**(CD: budesonide/corticosteroids & 5-ASA/corticosteroids in UC)**

Use **anti-TNF monotherapy** (or combination therapy with thiopurine)
or **ustekinumab** or **vedolizumab**
(or **tofacitnib** for UC as 2nd line)

Adapted from: AGA Institute Clinical Practice and Quality Management Committee. *Gastroenterology* 2013;145:1459-63.

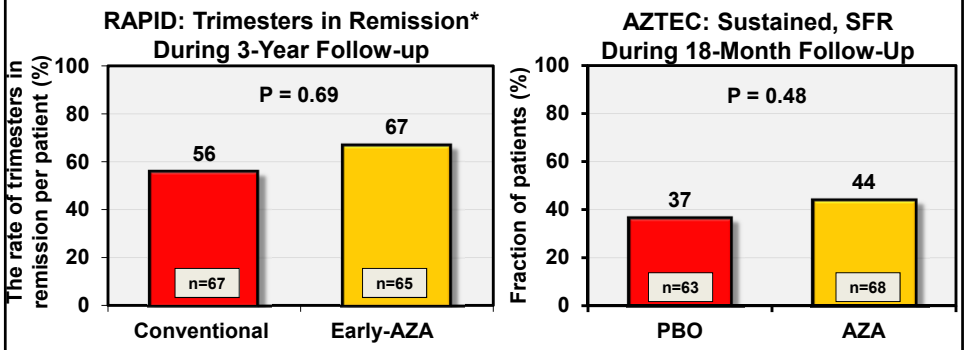
# AGA & CAG IBD Guidelines:

## Maintenance of Remission




Adapted from: AGA Institute Clinical Practice and Quality Management Committee. *Gastroenterology* 2013;145:1459-63.

## Little Benefit of AZA Compared to Standard of Care




- **RAPID: Prospective, randomized, OL, 24-centre study; N = 142 pts; CD duration < 6 mos (med = 2.5 mos), IS- and Bx-naïve, no previous surgery; ≥ 2 predictors of disabling disease; early-AZA is not superior**
- **AZTEC: Prospective, randomized, DB, 31-centre study; N = 131 pts; CD duration < 8 wks, IS- and Bx-naïve, AZA is not superior to PBO in early, inflammatory, luminal, AZA-naïve CD**

*9 trimesters, 4 months/trimester = 3 yrs

Cosnes et al. Gastro. 2013; 145 (4): 758-765; Panes et al. Gastro. 2013; 145 (4): 766-774

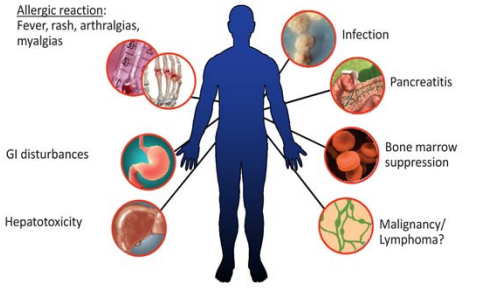
# Common Side Effects of Immunosuppressive Therapy

## Up to 30% of patients stop treatment because of side effects

- Nausea, vomiting, and malaise most common (early symptoms)
- Symptoms are usually mild, occur early in therapy, and improve over time
- Slower dose titrations or taking the drug with meals may minimize nausea
- If persistent symptoms, could consider switch to 6-MP (60% may improve)

Nielsen et al. *Aliment Pharmacol Ther* 2001;15:1699-708
http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-2036/issues
Su, Lichtenstein. *Gastroenterol Clin North Am* 2004;33:209-34
http://www.sciencedirect.com/science/journal/08898553
Lees et al. *Aliment Pharmacol Ther* 2008;27:220-7
http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-2036/issues

**Risk associated with azathioprine/6-mercaptupurine**




Kornbluth A, Sachar DB. *Am J Gastroenterol.* 2004;88:1371.
deBoer N et al. *Nature Clin Pract Gastroenterol Hepatol.* 2007;4:686.

# Safety Issues with Biologics

- **Anti-TNF's:**
  - Infectious complications
    - Latent Tb (CXR, PPD/IGRA)
    - Bacterial and granulomatous infections
    - Hepatitis B reactivation
    - No live vaccines
  - "Autoimmune"type reaction (lupus-like)
  - Contra-indications
    - severe CHF, demyelinating disease
- **VDZ/UST:**
  - generally safe with no increased risk of infections (same as placebo)
- **Tofacitinib**:
  - increased risk of HSV, DVT and MACE. Altered lipid profile.

## Potential Considerations for Choosing a Biologic ?

| Drug Factors |
|---|
| Clinical efficacy |
| Mucosal healing/fistula healing |
| Favourable safety profile |
| Durability of remission (dose optimization +/- TDM) |
| Immunogenicity (need for combo) |
| Rapid induction of remission |

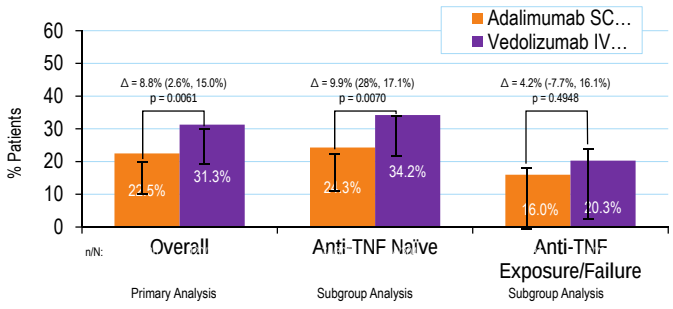
| Patient clinical factors at initiation |
|---|
| Active perianal disease |
| Pregnancy |
| Presence of EIM's |
| Age/co-morbidity |
| Tolerate IS Rx |
| Steroid refractory |

| Patient factors |
|---|
| Mode of administration |
| Ease of use/cost |
| Work/travel/time spent on Rx |

| Physician factors |
|---|
| Time on the market/ comfort level |
| Ease of use |
| Personal experience |

## Results of VARSITY: 1st Head to Head Trial (VDZ vs ADAL)

- Overall clinical remission at Week 52




Clinical remission: Complete Mayo score ≤ 2 points and no individual subscore > 1 point.
Full analysis set: includes all randomized patients who received at least 1 dose of study drug.
Anti-TNF subgroup analysis was prespecified and produced nominal p values.
anti-TNF: anti-tumour necrosis factor

# Biosimilars approved in Canada: New starts/forced switches

| ADAL | Amgevita™ | Hulio® | Hyrimoz® | Idacio® | Hadlima™ | Adalimumab Injection† |
|---|---|---|---|---|---|---|
| Company | Amgen | Mylan/Fujifilm BGP Pharma ULC | Sandoz (Novartis) | Fresenius Kabi | Merck/ Samsung Bioepis | Pfizer |
| Indications in adults (18+ yr) | RA, PsA, AS, PsO, UC, CD, HS, UV | | | | | |
| Indications in pediatrics (age, yr) | JIA(2+) CD(13+) HS(12+) UV(2+) | JIA(2+) CD(13+) HS(12+) UV(2+) | JIA(2+) | JIA(2+) CD(13+) HS(12+) UV(2+) | JIA(2+) HS(12+) UV(2+) | JIA(2+) CD(13+) HS(12+) UV(2+) |
| RCTs | PsO, RA | RA | PsO | PsO | RA | RA |
| Citrate-free | Yes | Yes | No | No | No | Yes |
| Needle Size | | | | | | |
| Syringe | 29G | 29G | 29G | 29G | 29G | 29G |
| Pen | 27G | 29G | 29G | 29G | 29G | 29G |

| IFX | Inflectra | Renflexis |
|---|---|---|
| Company | Pfizer | Merck |
| Indications in adults (18+ yr) | RA, PsA, AS, PsO, UC, CD, | |

- †Pfizer adalimumab injection is approved by Health Canada but not yet marketed.
  Primary endpoint for RCTs in RA is ACR20, for PsO PASI 75.
  ACR20, 20% improvement in American College of Rheumatology criteria; AS, ankylosing spondylitis; CD, Crohn's disease; JIA, polyarticular juvenile idiopathic arthritis; HS, hidradenitis suppurativa;
  PASI 75, 75% improvement in Psoriasis Area and Severity Index score; PsA, psoriatic arthritis; PsO, plaque psoriasis; RA, rheumatoid arthritis; RCT, randomized controlled trial; UC, ulcerative colitis; UV, uveitis.
  Adapted from Coghlan J et al. Journal of Pharmaceutical Sciences. 2021;S0022-3549(21)00080-0. Complete references to product monographs in notes.

# Practical tips and considerations

- Non-medical switching is safe and has the potential to save HC system resources[1]
- IBD guidelines do not recommend automatic substitutions and advise against nonmedical switching in patients with stable IBD doing well on the originator product[3].
- Patients should not be disadvantaged by switching (i.e., no extra out of pocket expenses, same access to therapeutic monitoring through FC and drug levels)[1,2]
- Switching is based on principles of no incremental costs by patient, and demonstrated cost savings to HC system[1]
- Switching should be done under medical surveillance only.
- There must be a respectful and informed conversation between the prescribing physician and patient prior to switching[2]
- If switching is initiated by someone other than the prescriber, notification must be given to the physician and patient[2]

- FC, fecal calprotectin; HC, health care; IBD, inflammatory bowel disease.
  1. Ontario Rheumatology Association. https://ontariorheum.ca/wp-content/uploads/Final_ORA_Position_on_Administrative_Switching_AND_FAQs.pdf. Accessed 25 February 2021;
  2. Canadian Rheumatology Association (CRA) Position Statement on Biosimilars. https://rheum.ca/canadian-rheumatology-association-cra-position-statement-on-biosimilars/. Accessed 25 February 2021. 3. Moayyedi P et al. J Can Assoc Gastroenterol. 2020;3(1):e1-e9.

# Consequences of the nocebo effect

Nocebo effects are phenomena associated with actual or perceived harm that occur because of patients' negative expectancies[1]

**May be caused by:**[1,2]

- Lack of awareness
- Knowledge gaps
- Misperceptions

**May lead to:**[1]

- Patient non-adherence
- Patient discontinuation
- Perceived increase in AEs or suboptimal efficacy

AE, adverse effects.

1. Colloca L et al. Front Pharmacol. 2019;10:1372; 2. Rezk MF and Pieper B. Rheumatol Ther. 2017;4:209–218.

# IBD:
# Chronic disease co-management

# Therapy Related Testing

- **Mesalamines**
  - Annual renal function monitoring.
- **Corticosteroids**
  - Document plan and use of corticosteroid-sparing therapy. Consider ophthalmology exam.
- **Thiopurines**
  - TPMT, CBC and liver function prior to initiating therapy. Routine CBC and liver function monitoring while on therapy.
- **Methotrexate**
  - CBC, liver, and renal function prior to initiating therapy. Routine CBC, liver, and renal function monitoring while on therapy.
- **Anti-TNF/Ustekinumab**
  - Tuberculosis ( TB) screening prior to initiating therapy with PPD skin testing and/or QuantiFeron-TB Gold assay. Chest X-Ray if high-risk and/or indeterminate PPD or QuantiFeron-TB Gold. Perform annual TB risk assessment and consider re-testing if high risk (including travel to endemic region). CBC, liver, and renal function prior to initiating therapy and periodic monitoring while on therapy.
- **Vedolizumab**
  - CBC, liver, and renal function prior to initiating therapy and periodic monitoring.
- **Tofacitinib:**
  - CBC, liver, lipid profile and renal function prior to initiating therapy. Routine CBC, liver, and renal function monitoring while on therapy. Consider stopping OCP. Shingrix vaccination.

# Pregnancy

- Avoid antibiotics and corticosteroids in the 1$^{st}$ trimester
- Biologics and thiopurines and 5-ASA's (**not MTX/tofacitinib**) are safe in pregnancy and with breastfeeding.
- No live vaccines (for 12 months) in babies exposed to biologics (no Rotavirus vaccination)

# Vaccinations

Patients with immune-mediated disorders should be offered age and gender appropriate vaccinations[1]

Immunosuppressive medications and biologics may cause an attenuated response to vaccines[1]

Live vaccines should be avoided[1]

Vaccination strategies should be part of general health maintenance checklists for IMID patients

There is no evidence that vaccination worsens the course of or causes flare of IBD[1]

IMID, immune-mediated inflammatory disease.
1. Papp KA et al. J Cutan Med Surg. 2019;23(1):50-74.

# COVID-19

Increased risk of complications with thiopurines/prednisone !

Highlighted themes of accepted statements related to SARS-CoV-2 vaccination for patients with IBD by the International Organization for the Study of Inflammatory Bowel Disease (IOIBD)

- Patients with IBD **should be vaccinated** against SARS-CoV-2.
- The best time to administer SARS-CoV-2 vaccination in patients with IBD is at the **earliest opportunity to do so**.
- SARS-CoV-2 vaccines including messenger RNA vaccines, replication in competent vector vaccines, inactivated vaccines and recombinant **vaccines are safe to administer** to patients with IBD.
- SARS-CoV-2 vaccination **should not be deferred** because a patient with IBD is **receiving immune-modifying therapies**.
- Patients with IBD vaccinated with SARS-CoV-2 should be counselled that **vaccine efficacy may be decreased when receiving systemic corticosteroids/anti-TNF's**

## Disease Flares

- **UC patient with flare:**
  - rule out infection, routine labs/CRP/FCP
  - Ensure compliance. If already on 5-ASA, increase dose or add enema.
- **CD patient with flare**
  - Rule out infection, routine labs/CRP/FCP
  - If symptoms worsening on prednisone taper, can increase the dose.
- Speak with GI if any concerns (existing or new patients)
- IBD pt on high dose CS, IM, anti-TNF
  - High index of suspicion if fever/infectious symptoms

## Summary

- Use red flag questionnaire and CRP/FCP as adjunct testing for faster GI access/earlier diagnosis
- Mucosal healing is the target → FCP to help guide treatment
- Increasing use of biologics (and biosimilars) → forced anti-TNF switching coming soon
- Communication with primary care is crucial for appropriate co-management

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# Thank-you !

Questions/Comments ?

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