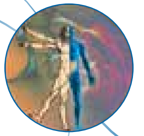

SESSION 4

Combination Therapy with Biologics: Does one size fit all?

CASE-BASED BREAKOUT WORKSHOP

The patient is a 31-year-old male smoker working as a French teacher. He presents to the ER with a two-month history of right-lower-quadrant (RLQ) pain, five to eight non-bloody liquid stools per day, perianal discharge and a 4.5 kg (10 pound) weight loss.

In the emergency department, he is seen by the GI service.

On physical exam, the RLQ is tender, there is a thickened bowel loop and small perianal fistula.

Laboratory investigations show:

- White blood cell count of 14 x 109/L
- Hemoglobin 119 g/L
- C-reactive protein (CRP) 72 g/L
- Stool culture and sensitivity and *C. difficile* are negative

A computed tomography scan of the abdomen and pelvis showed: 40 cm thickened terminal ileum and proximal colon with mucosal enhancement; no abscess; and small perianal fistula

Colonoscopy reveals deep, discrete ulcerations of the terminal ileum, ascending and rectosigmoid colon.

He is started on prednisone.

You see him in the office 1 week later. He feels better but his symptoms persist. The biopsy results are compatible with IBD.

Decision Node 1

- What therapy do you consider initiating at this time?

After discussion, the patient is ready to start a biologic and he says he understands the benefits and risks. Because he often travels, he wishes to have a subcutaneous agent. You therefore start him on adalimumab, in combination with 6-mercaptopurine. You see him three months later and he is doing well. He comes for a subsequent follow-up at nine months. At this visit, he says that he has done a lot of reading and is worried about combination therapy and wishes to stop one of the two agents.

Decision Node 2

- Do you recommend stopping one agent and if so which one?

You reassess disease activity. Complete blood count, fecal calprotectin and CRP are all normal. A colonoscopy shows scarring in the rectosigmoid and ascending with normal remaining colon

and distal ileum. You inform the patient he is in remission and decide he can stop the thiopurine.

Six months later, the patient returns to your office complaining of three to four loose stools per day, with abdominal pain. The perianal fistula is inactive. His hemoglobin is 121 g/L, CRP is 22 g/L and fecal calprotectin is > 2100 mcg/g.

Decision Node 3

- How would you manage his biologic therapy?

You measure adalimumab levels and they are at 40 mcg/mL with no antibodies.

Decision Node 4

- What do you do at this time?

You discuss the possibility of switching biologic therapy. The patient agrees, and says that he still wishes to have a subcutaneous agent. You prescribe ustekinumab.

Decision Node 5

- Would you prescribe immunosuppressant combination therapy with ustekinumab?
- If the decision has been to switch to vedolizumab would you have added an immunosuppressant to that regimen?