SESSION (4)

Optimizing Management in IBD: De-Escalating Therapy – What are the Rules?

The Rules of Stopping Biologics: A North American Perspective

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Biologic drug therapy has greatly advanced the treatment of inflammatory bowel disease (IBD). Use of tumour necrosis factor-α (TNF-α) antagonists in combination with immunosuppressives has become a standard of care for high-risk patients with ulcerative colitis or Crohn's disease. More recently, natalizumab and vedolizumab have provided additional alternatives. It is critical to note that these therapies have been established on the backbone of rigorously conducted, randomized, controlled trials.

Several arguments can be made to advocate for discontinuation of biologic therapy in a responding patient, the most common of which are safety and cost. Pregnancy is another special case. However, critical examination of these arguments reveals a weak scientific case for discontinuation. First and foremost, well-designed withdrawal studies have not been conducted, so the evidence base does not exist to support this practice. Discontinuation of drug therapy in high-risk patients runs the hazard of losing established benefit in patients who generate the most morbidity and greatest costs. Drug acquisition costs are not the whole story.

While it can be argued that re-introduction of the previous agent might re-capture response in a high proportion of patients, we all know only too well of the problem of immunogenicity associated with intermittent use of biologics. The only studies conducted specifically to address this question are open-label trials that are highly susceptible to both bias and confounding. Without data we should not recommend this to our patients.

It is noteworthy that all available IBD biologics are Federal Drug Administration Category B drugs for pregnancy. In respect to other safety concerns I will argue that these have been greatly overstated and can be mitigated by good medical practices.

To paraphrase a former American president, "In continuing biologics in high-risk patients we have only to fear Fear itself."

In my practice I generally continue biologic drugs in high-risk patients.