Editors,

We were interested to read the report by Biemans et al detailing the efficacy of tofacitinib in a real world, largely biologic experienced, ulcerative colitis (UC) population.\(^1\) Here we describe our experience with tofacitinib in a biochemicaly severe and biologic experienced Australian UC population. At 16 weeks, our response rate was 64% with remission seen in 30%, albeit with the use of higher tofacitinib maintenance dosing for a third of patients.

A total of 26 patients were identified, 25 (96%) were biologic-experienced (anti-TNF or vedolizumab), and 19 (73%) had previously failed more than one biologic. One patient was biologic naive. 13 (50%) had Montreal E3 at diagnosis, and 20 (77%) had a history of acute severe UC. 14 (54%) patients were on concomitant steroids at time of tofacitinib commencement. 25 (96%) patients underwent standard induction for 8 weeks at 10mg BD, with one patient receiving 20mg BD due to acute severe UC. At time

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of last follow-up (13.3 months (range 2-25 months)), 10 (38%) patients were on a dose of 5mg BD, 10 (38%) patients were on 10mg BD and six (23%) had ceased tofacitinib due to inadequate response.

Clinical response was defined as a reduction of partial Mayo score >2, and remission as partial Mayo 0-1, with no rectal bleeding present.² By week 16, 8 (30%) had achieved remission, and 9 (34%) had treatment response. At the end of follow up 15 patients (58%) were in remission with one (4%) having response but not remission. 6 (23%) were non responders. Four (15%) patients had less than 16 weeks of therapy at the time of data analysis [figure 1]. Eleven (42%) patients had faecal calprotectin (FC) data available. Median FC levels pre tofacitinib treatment were elevated at 325 (5-8000) and fell to 35 (5-407) post induction treatment.

Four (15%) patients were on combination vedolizumab and tofacitinib. Three of these had a partial response to vedolizumab initially and tofacitinib was added, one was commenced on tofacitinib initially with only partial response and vedolizumab was added. At the end of follow up, two (50%) were in clinical remission and two (50%) had clinical response.

Adverse events encountered include 3 (11%) patients with Varicella Zoster infection, and 1 (4%) with cytomegalovirus colitis. A skin reaction requiring hospitalisation was attributed to tofacitinib in one patient and the drug was ceased.

In a single centre cohort of biologic experienced patients with severe UC, tofacitinib was effective at inducing remission. Response rates at 8 weeks were high with most patients achieving remission by week 16. This appeared to be a durable response with 15 (58%) in remission at the end of follow up. A significant proportion of patients were on higher maintenance doses (10 mg BD), which may have contributed to the higher remission rates observed in this cohort. Physicians can be optimistic about tofacitinib as a treatment option for moderate-severe UC even in biologic experienced patients, although higher dosing may be required to optimise response and remission rates. Further data about concomitant use of vedolizumab and tofacitinib may prove to be beneficial in refractory patients.

References:


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Figure 1: Clinical Assessment of Response
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