

Are anti-TNF agents safe in cirrhotics? The question remains unanswered

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We read with great interest the original article by Kapila *et al.*,¹ evaluating the safety of anti-tumor necrosis factor- α (TNF) agents in patients with compensated cirrhosis in a case-control study design. The analysis showed no increase in the rate of decompensation, liver transplant or liver-related mortality or infection in the anti-TNF group. We would like to congratulate the author for conducting a study on this less common but important topic as there is a paucity of data regarding the safety of anti-TNF agents in cirrhotics. However, there are a few issues that need to be addressed.

First, the study is a retrospective analysis, which has a risk of selection and attrition bias. Patients who had a decompensation, infection or mortality may have presented to another hospital.

Second, the median duration of follow-up in the anti-TNF group is 45.2 months. Previous studies on the risk of new cancer or cancer recurrence among patients exposed to anti-TNF therapy showed that malignancy develops after a median duration of 6.8–11.5 years after initiation of anti-TNF.^{2–4} Hence, longer study duration was required to study the incidence of malignancy in the anti-TNF group.

Third, there are no data on the liver function tests of the patients on anti-TNF. The study mentions that there was no difference in new-onset decompensation between the two groups. However, it is possible that patients in the anti-TNF may have developed drug-induced liver injury/hepatitis, which may contribute to significant morbidity and drug discontinuation.

Finally, the author concluded that there was no difference in the infection rate between patients on anti-TNF and the control group (21.3% *versus*

15.4%, $p=0.52$). However, this conclusion needs to be taken with caution. In a previous systematic review and meta-analysis of 71 randomized controlled trials (RCTs), use of anti-TNF was associated with significantly increased risk of any infections – odds ratio (OR) = 1.20, 95% confidence interval (CI): 1.06–1.36, $I^2=46\%$; serious infections – OR = 1.25, 95% CI: 1.01–1.55, $I^2=0\%$; and tuberculosis – OR = 3.29, 95% CI: 1.48–7.33, $I^2=0\%$, with a moderate level of evidence.⁵ Hence, patients on anti-TNF should be closely monitored for infections. Further larger prospectively maintained data are required to study the safety of anti-TNF in patients with cirrhosis.

Author contributions

Conceptualization, drafting, critical revision and final approval were performed by Suprabhat Giri.

Conflict of interest statement

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