Editorial: alfapump—an alternative to large-volume paracentesis for patients with refractory ascites? Authors’ reply

In their editorial, S. Macdonald and R. Jalan compare the results of the Post Marketing Surveillance Registry (PMSR) study with the outcome of the randomised controlled trial (RCT). However, it is important to mention that the observation period in the RCT was 6 months, whereas in the PMSR it was 12-24 months. A higher number of adverse events in the PMSR study is therefore not unexpected and, at least partially, explained by the duration of the observation period. Furthermore, and as mentioned in the editorial, patients in the PMSR study suffered from more advanced liver disease. Of the 27 alfapumps explanted in the PMSR study population, a significant number of pumps were removed independent of an adverse event: 9 pumps were explanted due to liver transplant and one because of no more need.

Worsening of kidney function has been observed in the PIONEER study, as well as in the RCT and in the PMSR study. Compared to the standard treatment group, patients in the alfapump group had a higher probability of acute kidney injury in the RCT, especially within the first week after implantation of the pump. The pathophysiology of this kidney function alteration remains poorly understood. In case of suspected hepatorenal syndrome, albumin...
replacement in combination with terlipressin\(^5\) has been effective in clinical practice in several patients with an alfapump.

After the implantation of the alfapump, an increase in ascites production and drainage has been observed in the RCT as well as the PMSR study. Taking into account the albumin content in the ascites (usually several grams per litre), this may aggravate loss of albumin over time and consequently lead to the observed decrease in albumin. Bearing in mind that sarcopenia is a frequent and prominent finding in this patient population, maintenance of protein balance is crucial to avoid further aggravation of sarcopenia. In addition to a thorough assessment of the nutritional status of these patients\(^6\) before implantation of the alfapump, nutritional deficits should be counterbalanced and especially insufficient protein intake compensated with an increased protein intake as recommended in cirrhotic patients.\(^7\) The potential benefit of regular albumin replacement as suggested in the editorial should be investigated in a prospective trial.

Overall, there is a clear need for further technical improvement of the alfapump system, and this has already been achieved in part by the new peritoneal catheter that has virtually eliminated the blockage of the peritoneal catheter (internal analysis of the producer). In addition to technical improvement, management of patients with an alfapump has to be improved to further decrease the rate of complications.

**ACKNOWLEDGEMENTS**

The authors’ declarations of personal and financial interests are unchanged from those in the original article.\(^2\)

**ORCID**

G. Stirnimann http://orcid.org/0000-0003-3447-264X
A. De Gottardi http://orcid.org/0000-0002-4401-2340

**REFERENCES**


**LINKED CONTENT**

This article is linked to Stirnimann et al and Macdonald and Jalan papers. To view these articles visit https://doi.org/10.1111/apt.14331 and https://doi.org/10.1111/apt.14390.

**EDITORIAL: ANTI-TNF THERAPY AND MYOPENIA IN CROHN’S DISEASE—ANOTHER STEP TOWARDS PERSONALISED MEDICINE**

The use of anti-TNF medications in the treatment of Crohn’s disease has now become standard and subsequently we know increasingly more about their efficacy and outcomes. Despite some years of experience, there is still a primary nonresponse rate of 10%-30% and a secondary nonresponse of 5% per patient year.\(^1\) Dosing schedules of each medication tend to be standard, and not personalised, with no one biomarker being available to predict those who are most at risk of primary and secondary nonresponse. It is increasingly evident that outcomes in Crohn’s disease are improved by intervening at an early inflammatory stage to prevent future complications.

The use of a powerful medicine that may not work exposes a patient to potentially unnecessary risks. It also wastes time and opportunity when another drug class or dosing schedule may be more appropriate. Dosing to body weight and even potentially to body mass index (BMI) makes intuitive sense, but pharmacokinetic studies tell a very different story: anti-TNF levels are highly variable