

Invited editorial: Alimentary Pharmacology & Therapeutics

Treatment of refractory ascites with an automated low-flow ascites pump in patients with cirrhosis

alfapump: An alternative to large volume paracentesis for patients with refractory ascites?

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Potential conflict of interest: Prof Jalan was the Chief Investigator for a Sequana Medical sponsored trial of alfapump for refractory ascites (J Hepatol. 2017 Jun 21. pii: S0168-8278(17)32080-9). Rajiv Jalan has on-going research collaboration with Yaqrit and Ocera. He is also the founder of UCL spin-out company Yaqrit Ltd. and Cyberliver Ltd. SM has nothing to disclose.

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Refractory ascites (RA) is a serious complication of cirrhosis that is associated with a poor prognosis and impaired quality life (QoL).^{1,2} Liver transplantation is the only definitive treatment for RA but limitation in organ supply has resulted in large volume paracentesis (LVP) and transjugular intrahepatic portosystemic shunt (TIPSS) becoming the mainstays of therapy.^{3,4} LVP, whilst relatively safe is associated with high healthcare costs due to frequent hospital admissions and a negative impact on both QoL and nutrition.^{5,6} TIPSS is contraindicated in a significant number of patients with RA and in about 30%, it will be ineffective and/or result in moderate-severe hepatic encephalopathy.^{7,8} Clearly, new therapies for RA are required.

The alfapump (Sequana Medical AG, Zurich, Switzerland) is an implanted closed pump system that transports ascites from the peritoneal cavity to the urinary bladder via firstly a tunneled peritoneal catheter and then a tunneled bladder catheter. The safety and efficacy of the alfapump system was demonstrated in the PIONEER study in 2011.⁹ The data regarding safety and efficacy were confirmed in a recently published randomized clinical trial comparing the alfapump with LVP.¹⁰

Stirnimann et al., present real world data collected through a post marketing surveillance registry from a European multi-center prospective observational study of 56 patients with refractory ascites, in whom a TIPSS was contraindicated, who underwent alfapump insertion for RA. Follow up was for a minimum of 12 months. Whilst the efficacy of the alfapump was clearly demonstrated, with a reduction in median number of paracentesis per month

from 2.17 prior to the study to 0.17 after pump insertion, they also reported significant procedure-related complications with 17 patients (21.4%) requiring at least one reintervention and 27 patients (48%) required explantation of the device, 17 (30.3%) of whom due to a SAE. This is higher than the 11% reported in the recently published randomized controlled trial.¹⁰ The most common technical problem was blockage of the peritoneal catheter which occurred in 13 patients (23.2%). 23 patients (41.1%) patients died during the study of whom 7 patients (12.5%) died after explantation of the device. Additionally, an elevation in serum creatinine (46.6 μ mol/l) and a reduction in serum albumin (2.3g/L) was demonstrated, which is consistent with previously published data.¹⁰ The increase in creatinine at 3 months, however, was not shown to effect survival. This suggests that albumin replacement, as is the standard of care for patients undergoing large volume paracentesis, should be routinely administered for patients being treated with alfapump. The quantity of albumin and schedule of replacement remains to be determined. The higher complication rate in the present study may be related to the sicker group of patients included [MELD score (13.6 v 12.2); Childs-Pugh Grade 3 (24.8% v 11.1%)] compared with the randomized controlled trial.¹⁰

This real world study confirms the data from the randomized trial. Once again efficacy of the system has been demonstrated. With further improvements in the device characteristics and introduction of routine albumin replacement, alfapump could emerge as a real alternative to large volume paracentesis.

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