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Long-Term Follow-up of Patients with Cirrhosis and Recurrent Ascites Treated with an Automatic Low Flow Ascites Pump (alfapump) in North America.

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Abstract Text

Background: Many cirrhotic patients with recurrent ascites are unsuitable for TIPS insertion or cannot attend repeat large volume paracentesis (LVP). Therefore, this study aimed to assess the North American experience of long-term efficacy, safety and clinical outcome of patients who received an alfapump as a definitive treatment for recurrent ascites.

Methods: Prospective study of cirrhotic patients with recurrent ascites, not suitable for TIPS, who received an alfapump. All patients were monitored for ascites control, laboratory abnormalities, adverse events related to pump function, and underlying cirrhosis, and survival for 12 months (M).

Results: 30 patients (age 60±10 years, 57% male, MELD 15.1±5.1) received alfapump mostly via an interventional radiology approach (97%), together with long-term prophylactic antibiotic. Albumin infusions were given ad hoc as per investigator decision. The mean annualized ascites volume removed by the pump was 294.54±115.97 L/y (n=23), reducing the mean annualized LVP rate from 24.44±16.03 to 2.75±4.60 (N=30) in the 3M pre- and 12M post-pump implant periods, respectively. All surviving patients experienced improved nutritional status (prealbumin increased from 87.8±37.5mg/L baseline to 102.9±45.3mg/L at 3M, p=0.041) and better quality of life as measured by chronic liver disease questionnaire (CLDQ) and ascites questionnaire (Ascites Q). 22 patients had ≥1 severe adverse events during their follow-up in 12M, either related to device/pump implantation or therapy (implant site infection-14, cellulitis-1, skin erosion over pump-1, pump setting issues -10 or malfunction-4, catheter malfunction-8, fluid leakage around catheter-1, postop bleed-1, SBP-1) or to underlying cirrhosis (stage 2 acute kidney injury (AKI)-6, other infections-8, increase in MELD >5points:17). 8 patients needed 9 pump exchanges mostly due to blocked pump or poor communication with charger. Eventually, 10 pumps were explanted in 12M (infection of pump/catheter/pump pocket or systemic-5, liver transplant-1, erosion-1, fluid leakage-1, pump malfunction-1, no longer needed-1). 4 deaths occurred in the 12M follow-up, related to advanced cirrhosis:1, AKI:1, bacteremia:1 and septic shock:1.

Conclusion: Alfapump is effective in removing ascites and reduces LVP requirement significantly. Device issues are being improved with better pump and catheter designs. Cirrhosis related complications seem no more frequent compared to published rates with alfapump in situ. Patients who remained alive had improved nutritional status and quality of life. Alfapump insertion can be a definitive treatment for recurrent ascites, especially in patients who are not TIPS candidates.

		Baseline	1M	3M	6M	9M	12M	P: BL vs.12M
CLDQ	n	28	28	25	20	18	18	
		3.88±1.21	4.98±1.00*	4.88±1.12*	4.84±1.19	4.17±0.98	4.46±1.11	0.072
Ascites Q	n	27	27	25	19	17	17	
		51.7±21.9	26.7±18.6*	32.2±18.4*	34.7±18.8	43.5±18.9	38.7±18.3	0.006

Improvement: CLDQ=higher value, Ascites Q=lower value. *P <0.001 vs. BL

Disclosures

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