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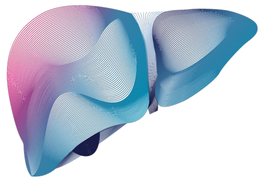

The Effects of alfapump on Ascites Control and Quality of Life in Patients with Cirrhosis and Recurrent or Refractory Ascites: Pivotal Trial Results

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Introduction

1

- The standard of care for recurrent or refractory ascites in cirrhosis is repeat large volume paracentesis (LVP)
- The alfapump system provides slow but continuous paracentesis via a subcutaneous pump
- The alfapump system has been shown to be a possible alternative for control of ascites in selected patients with cirrhosis and recurrent or refractory ascites (1,2).

Aim

2

- To assess the effects of alfapump on ascites control and quality of life (QoL) in patients with cirrhosis and recurrent or refractory ascites .

Method

3

- Patients with cirrhosis and recurrent or refractory ascites who required ≥ 2 paracenteses in the previous 3 months and refused or had contraindications or for TIPS were enrolled.
- Patients who served as their own controls must have ≥ 5 paras in 3 months prior to alfapump implantation
- Patients were given prophylactic antibiotic while the alfapump was in situ. Probiotic was also given for the first 6 months
- The 3-month immediate post-implant period was the stabilization period after implantation procedure
- The 3-month pre-implantation period was compared to the 4-6-month period post-implantation
- Data collected were demographics, pre- and post- implantation albumin use, ascites control, safety, QoL and ascites symptoms using SF36 and Ascites Q questionnaires, respectively
- Primary efficacy end point: reduction in paracentesis requirement
- Primary safety end point: pump system adverse events that resulted in intervention, explant or death.

Conclusions

5

- The alfapump system was very effective in the control of ascites, virtually eliminating the need for LVP.
- There is associated improvement in physical aspect of quality of life
- Patients with the alfapump need close monitoring for the development of acute kidney injury (AKI) or infection, which must be treated promptly to prevent adverse outcomes.
- In carefully selected patients with recurrent or refractory ascites, the alfapump is an alternative to repeat LVP.

Acknowledgements

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References

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2. Bureau C, Adebayo D, Chalret de Rieu M, et al. Alfapump® system vs. large volume paracentesis for refractory ascites: A multicenter randomized controlled study. J Hepatol. 2017 Nov;67(5):940-949.

* Deceased

Results

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Table 1: Patient Demographics & Baseline Laboratory data

Parameter (n=40)	Value
Age (years)	63.6 ± 9.5
Gender (Male) (%)	65%
Etiology of Cirrhosis* : Alcohol : NASH : Viral hepatitis : Others	 47.5% 37.5% 12.5% 11.0%
Hemoglobin (g/L)	110.7 ± 20.5
WBC (10^6/L)	5.1 ± 1.6
INR	1.4 ± 0.3
Na (mmol/L)	136.3 ± 4.5
Creatinine (µmol/L)	95 ± 23
AST (IU/L)	37 ± 16
ALT (IU/L)	22 ± 12
Bilirubin (µmol/L)	23 ± 13
Albumin (g/L)	35 ± 5
MELD-Na score	15.2 ± 3.8
CPT score	7.9 ± 0.97

* Some patients may have ≥ 1 etiology of cirrhosis

Table 2: Pertinent Medical History

Parameter (n=40)	Value
Past history of: : renal failure : encephalopathy : SBP : UTI : variceal hemorrhage	 17.5% 40% 7.5% 2.5% 20%
Ascites duration (M)	15.7 ± 14.8
ECOG status : 0 : 1 : 2 : 3 : 4	 5% 37.5% 42.5% 15% 0%
In hospital in past 3M	25%

Figure 1: Co-Primary Efficacy Endpoints

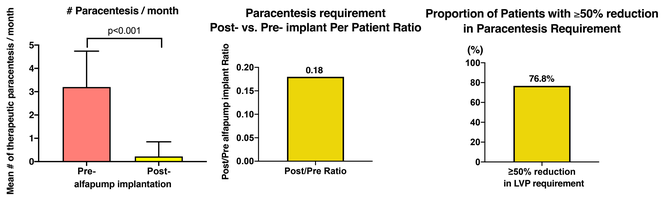


Figure 2: Ascites Parameters

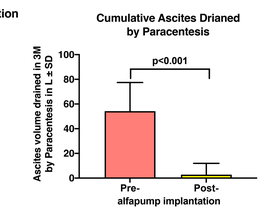


Figure 3: Quality of Life

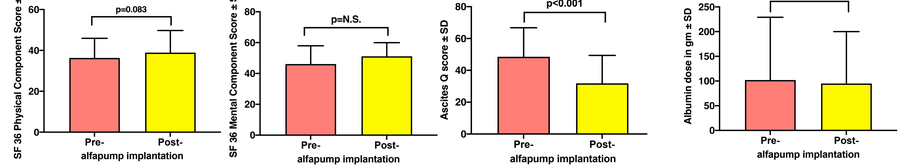
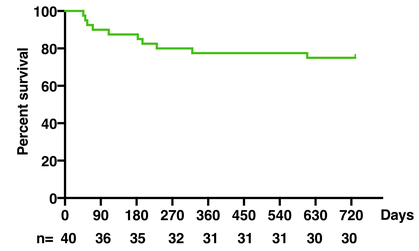
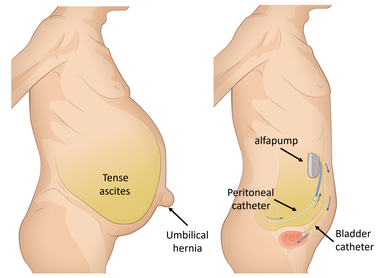


Table 3: Primary Safety Endpoints

Category	Pre-Implant (-3 months)	Post-Implant (+ 6 months)
Pump explants (total) : Skin erosion : Bladder discomfort	-	6 3 3
Deaths (total) : Covid : Cardiac arrest : End-stage cirrhosis : Hemoperitonium : GI Bleed	2 - - 1 - 1	7 2 1 3 1 -
SAEs (total) : Implant, pump, procedure related : AKI -stage 1/2/3 : Infection *all serious* *ascites related-serious*	n=17/11 pts - 4 2 1	n=81/24 pts 6 16/4/2 3 2
Major AEs (total) : AKI > stage 2 : HRS : HE> stage 2 : SBP : Recurrent/refractory infections	5 0 0 4 1 0	17 2 2 7 3 3

Figure 4: Survival





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Cirrhosis and complications
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