

Case report : treatment of a 69-year-old patient with refractory ascites due to liver cirrhosis with a new medical device – The ALFapump® System

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Introduction

Followed by hepatic encephalopathy and gastrointestinal hemorrhage, ascites is the most common complication and leading reason for hospitalization among patients with liver cirrhosis^{(1) (2)}. Standard ascites therapy includes sodium chloride restriction and diuretic treatment, but diuretic effectiveness is somewhat limited as its use is associated with the occurrence of hepatorenal syndrome, electrolyte abnormalities, azotemia and hepatic encephalopathy⁽³⁾. In many cases, ascites becomes refractory to diuretics with disease progression. Established treatment methods for refractory ascites due to liver cirrhosis include paracentesis and, in selected patient groups, a Transjugular Intrahepatic Portosystemic Shunt (TIPS). Although complication rates of paracentesis are low⁽⁴⁾, the procedure reduces the patient's quality of life and can also contribute to circulatory dysfunction⁽⁵⁾. It has been shown that TIPS is more effective in comparison to paracentesis in terms of reducing mortality and complications, such as gastrointestinal bleeding, spontaneous bacterial peritonitis and hepatorenal syndrome⁽⁶⁾, but its use is limited by various contraindications, both absolute and relative, such as portal vein thrombosis, episodes of hepatic encephalopathy in the patient's history and high-grade heart failure. Several other methods, such as a peritoneovenous shunt (e.g. Denver shunts), have been tested in the past but have not been used much in clinical practice due to their high complication rates⁽⁷⁾.

Here we report on a patient with alcoholic liver cirrhosis who was treated with a new therapeutic approach to refractory ascites – The ALFapump System (Automated Low-Flow Ascites Pump System, Sequana Medical, Zurich, Switzerland). The ALFapump is a fully implantable battery-powered device that moves ascites from the peritoneal cavity to the bladder. The pump is wirelessly recharged through the skin by the patient using a simple external charger. Communication with the pump for the setting of pump volume and downloading of pump data is also done via a wireless connection.

Case report

A 69-year-old man with alcoholic liver cirrhosis was admitted to our gastroenterological outpatient clinic. Cirrhosis had been diagnosed six years earlier and

ascites had been occurring for five months. Over the last four weeks, large volume paracentesis was performed three times with an average volume of 6 litres. The patient reported extensive alcohol abuse 20 to 30 years ago and on-going alcohol consumption limited to two or three glasses of beer per day. Co-morbidities of the patient included coronary heart disease with chronic heart failure (LVEF 40 %), arterial hypertension, chronic kidney disease (KDOQI Stage III), adult-onset diabetes and hyperlipoproteinemia. Concomitant medication included a platelet aggregation inhibitor, a renin inhibitor, a non-selective beta-blocker and a calcium channel blocker. Physical examination showed a massively tense abdomen, peripheral edema and atrophy of peripheral muscles. The initial laboratory findings revealed a nearly unimpaired function of liver synthesis (MELD 12) and a moderately increased serum level of -glutamyltransferase (365 U/L), as well as a normocytic anemia (hemoglobin 11.2 g/dL). Renal function was impaired (creatinine 1.6 mg/dL) due to pre-existing chronic kidney disease, which limited his allowed dosage of diuretics to no more than 50 mg spironolactone and 20 mg torasemide per day.

We informed the patient of his possible therapy options for refractory ascites, which included ongoing paracentesis, TIPS and the ALFapump System. Together, we decided on the ALFapump System. After reviewing the inclusion and exclusion criteria and obtaining informed consent, the patient was included in the PIONEER Study – a prospective, multi-center, open label, non-randomized study to investigate the safety and performance of the ALFapump System in patients with refractory ascites. Prior to implantation, another paracentesis with a volume of 6 liters was performed and spontaneous bacterial peritonitis along with any urological contraindications were ruled out. The implantation was performed under general anesthesia and lasted about 60 minutes.

The day after implantation, the patient developed an ascites leakage at the suture along with elevated infection parameters. Antibiotic therapy with ciprofloxacin (500 mg twice a day) was initiated and, because infection parameters were increasing, was switched to piperacillin/tazobactam (4/0.5 g twice a day). A single paracentesis and a secondary suture were performed, which ended the ascites leakage. From that point on,

the patient was free of infection signs. No more complications occurred and the patient was discharged in a good state. In the four weeks following implantation, we gradually increased the pump volume to 1200 ml per day. The follow-up period now includes 210 days and has moved a total volume of 161 litres. No additional paracentesis procedures were necessary, the ALFApump encountered no technical problems and there were no adverse events related to the implantation procedure or the pump function.

During the follow-up period, sonography of the abdomen showed no more than 200 – 300 ml of ascites, while body weight and abdominal girth remained stable. Laboratory findings revealed stable serum albumin concentrations and stable kidney function parameters (see Table 1). The patient reported an improvement in his quality of life and had no difficulties charging the pump.

Summary

This case report describes our experience using a new treatment approach for refractory ascites using the ALFApump System. In our patient, we had an initial issue with the wound healing after implantation; however, we've experienced no adverse events related to the pump over the longer course and no paracentesis procedures were necessary. Unexpectedly, and in spite of continuous ascites removal, serum albumin concentration remained stable. The ALFA-pump System should be considered as a treatment option for refractory ascites in selected patients.

References :

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TABLE 1 : LABORATORY FINDINGS PRE-IMPLANTATION AND DURING THE FOLLOW-UP TIME

PARAMETER	1 DAY pre-implantation	3 DAYS post-implantation	210 DAYS post-implantation
Sodium (mmol/l)	144	143	130
Potassium (mmol/l)	4.9	5.1	5.3
Hemoglobin (g/dl)	11.7	11.0	9.6
White blood count (g/l)	8.6	10.4	7.8
Platelet count (g/l)	178	217	291
Total bilirubin (mg/dl)	0.9	0.9	0.5
Albumin (g/dl)	3.5	2.8	3.2
INR	1.16	1.17	1.01
ALT (U/l)	16	20	17
AST (U/l)	24	26	24
GGT (U/l)	408	535	390
Creatinine (mg/dl)	1.64	1.86	1.55
Urea (mg/dl)	85	91	91