

# Improvement in Quality of Life and Reduction in Large Volume Paracentesis Requirement from the MOSAIC Study: a Multicenter, Open-Label, Prospective 3-Month Study of the ALFA pump System in Refractory Ascites

Florence Wong, University of Toronto, Toronto, ON, Canada; Emily Bendel, Mayo Clinic, Rochester, MN; Kenneth Sniderman, University of Toronto, Toronto, ON, Canada; Cathryn Shaw, Baylor University Medical Center, TX; R. Todd Frederick, California Pacific Medical Center, CA; Ziv J. Haskal, University of Virginia, VA; Arun Sanyal, Virginia Commonwealth University, VA; Sumeet K. Asrani, Baylor University Medical Center, TX; Jeroen Capel, Sequana Medical AG, CH; Patrick Kamath, Mayo Clinic, MN.

## INTRODUCTION

- Ascites is the most common complication of decompensated cirrhosis and occurs in 10% of all cirrhotic patients at any one time
- The presence of ascites is associated with further complications including early satiety and eventual malnutrition, and the risk for developing spontaneous bacterial peritonitis, hepatorenal syndrome, and abdominal hernias
- The presence of large ascites also requires many hospital visits for paracentesis.
- Thus, patients with ascites have poor quality of life
- The Automated Low Flow Ascites pump (alfa pump)(Sequana Medical AG) is a subcutaneous implantable rechargeable device that automatically transfers the ascitic fluid from the peritoneal cavity into the bladder. The ascites is then discharged as urine
- The alfa pump carries out a continuous low-rate paracentesis for approximately 16 hours per day and therefore keeps the ascites under control

## AIM

- To determine the efficacy and safety of the alfa pump system in the management of recurrent large ascites in cirrhotic patients
- To evaluate the quality of life (QoL) and large volume paracentesis (LVP) requirement at 3 months after alfa pump implantation

## MATERIALS & METHODS

- Prospective, open label, single arm multi-center study
- Cirrhotic patients with recurrent large ascites requiring LVP for symptom relief  $\geq$  once/month, and not eligible for TIPS.
- Safety: evaluated by incidence & severity of device and procedure related serious adverse events & survival
- Efficacy: evaluated by assessing LVP requirement and QoL after insertion of alfa pump.
- QoL: Evaluated using Ascites-Q questionnaire, an instrument used to measure quality of life in patients with ascites. Ascites-Q has been modified from the Polycystic Liver Disease questionnaire.

## RESULTS

Figure 1: Patient Disposition

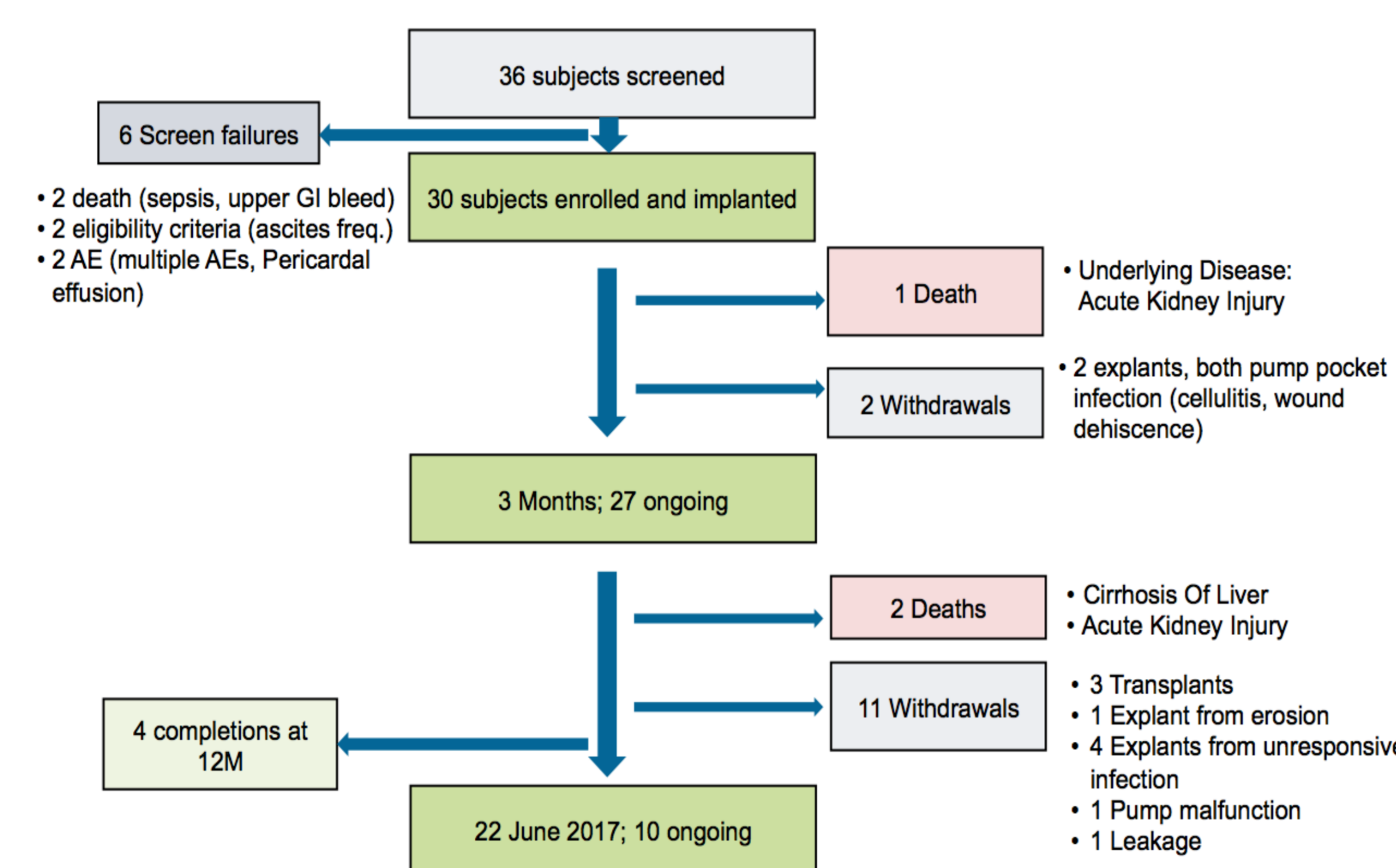


Table 1: Patient demographics

Parameter	Value
n	30
Age (years)	63 (32-72)
M : F	17 : 13
Etiology of cirrhosis	
alcohol	9 (30%)
NASH	9 (30%)
viral hepatitis	3 (10%)
alcohol/viral	3 (10%)
alcohol/NASH	3 (10%)
cholestatic	2 (6.7%)
others	1 (3.3%)
MELD at enrollment	15.1 ± 5.1

Figure 2: Change in Large Volume Paracentesis Requirement

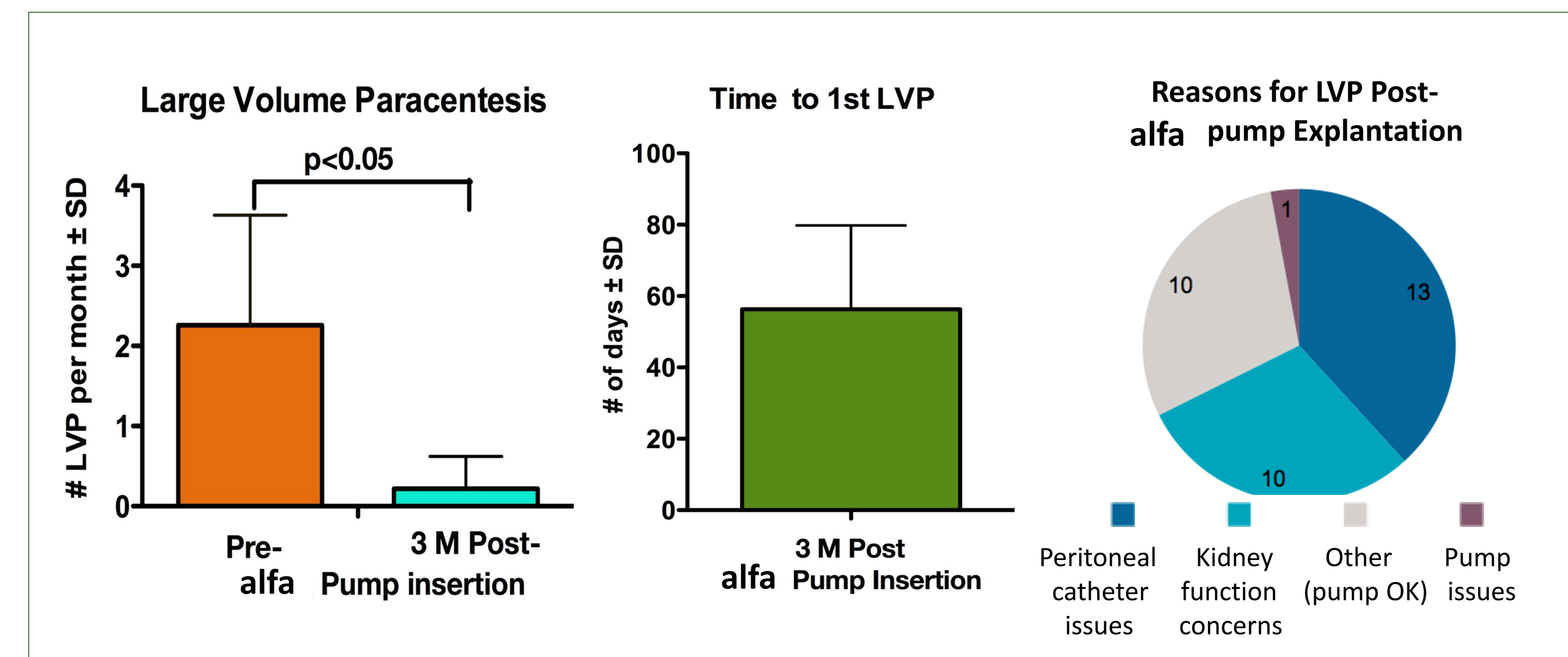


Figure 3: Serious Adverse Events

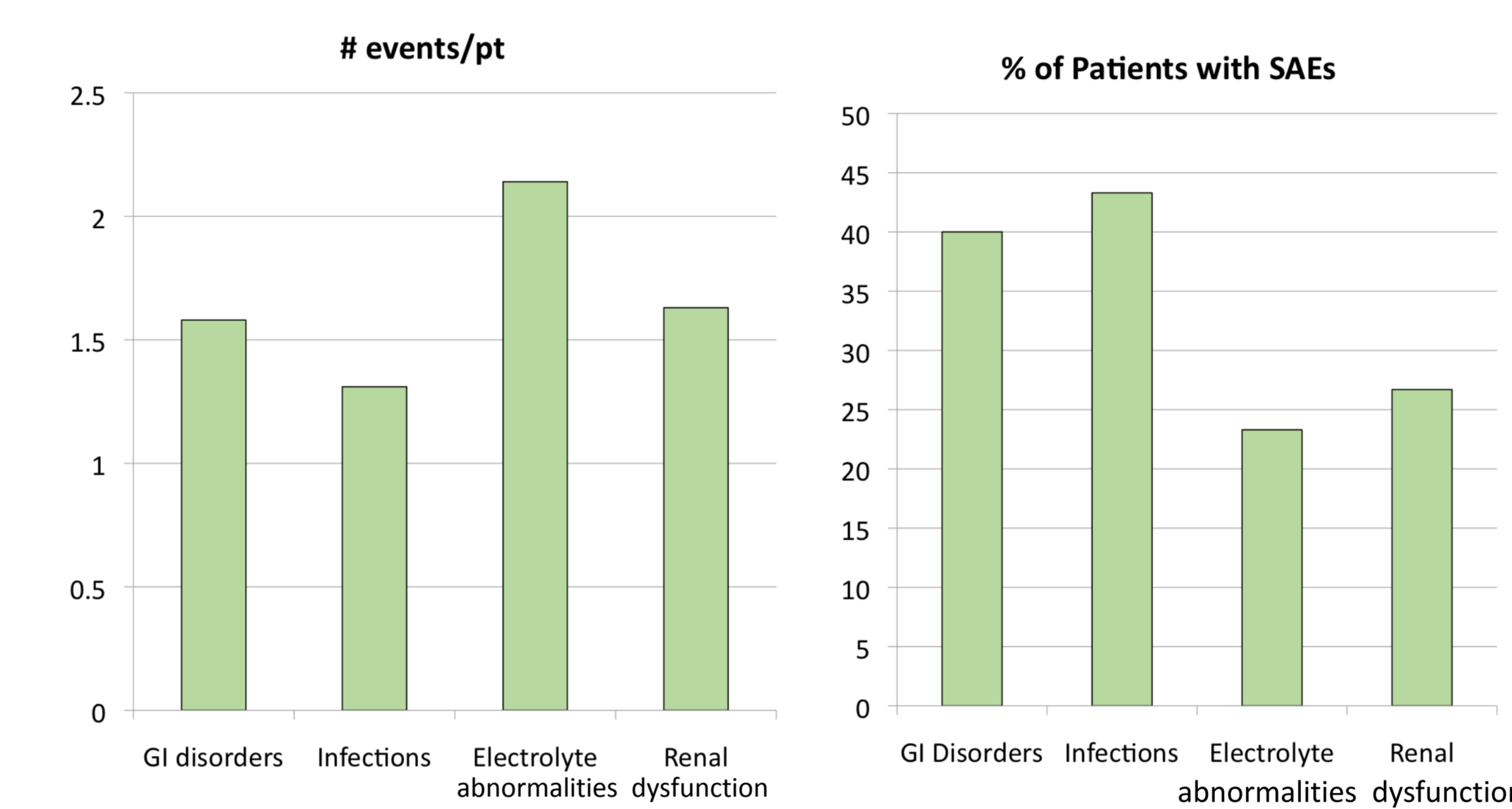


Figure 4: Quality of life changes

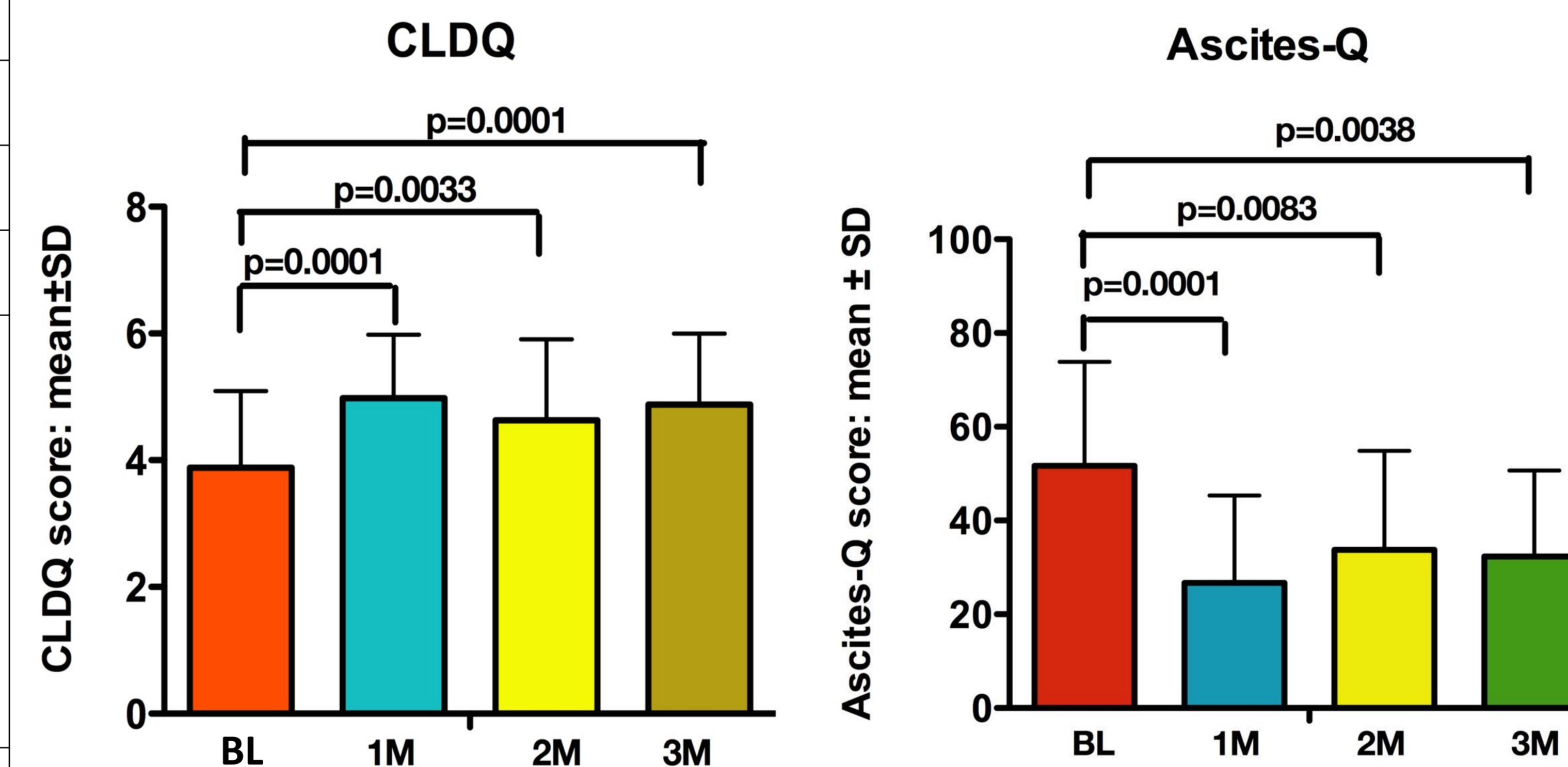
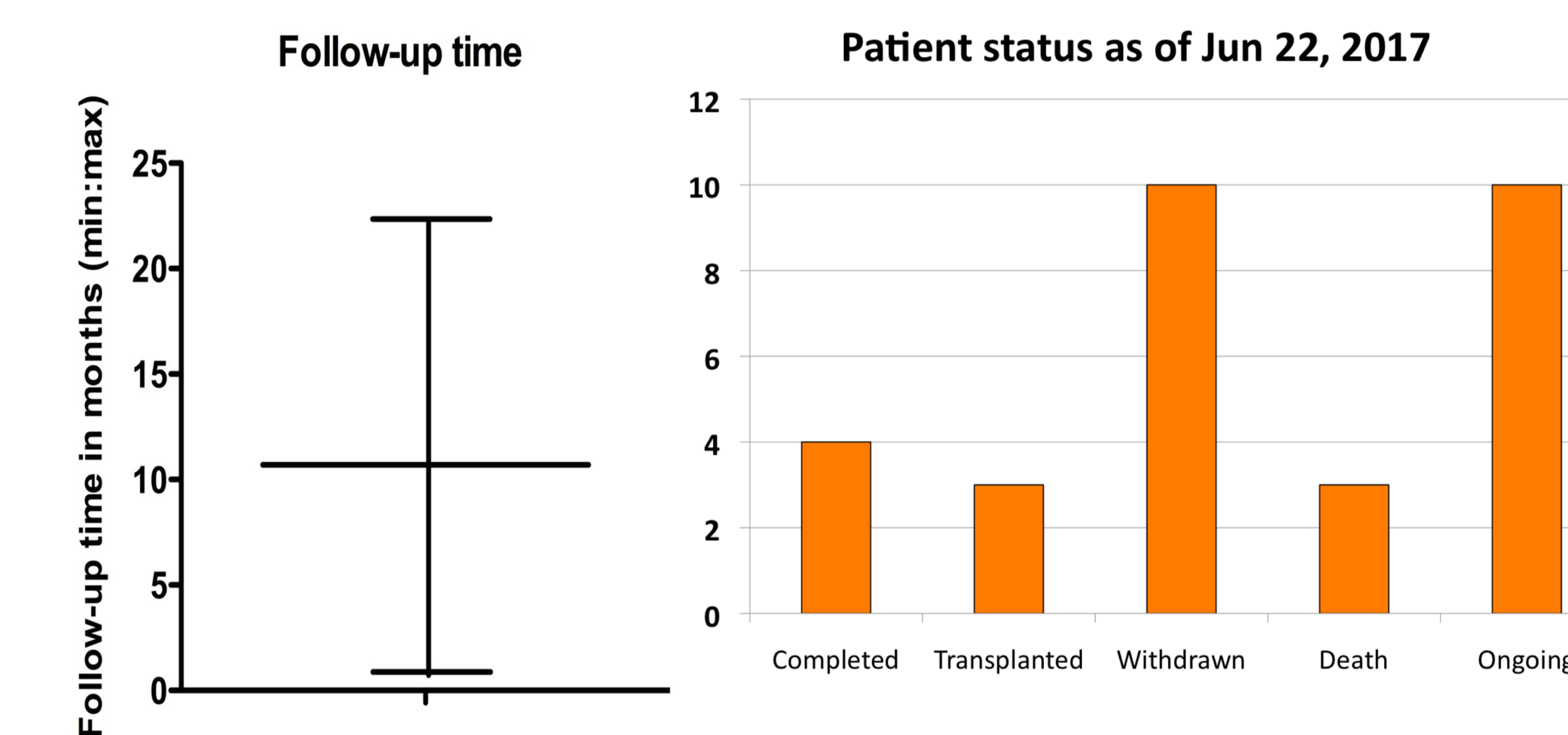


Figure 5: Patient Outcomes



## CONCLUSIONS

- In this North American study, the implantation of an alfa pump resulted in improvement of ascites control
- Clinically relevant changes in QoL, as measured by CLDQ and Ascites-Q, improved significantly as early as 1 month after alfa pump implantation and continued through 3 months
- Mortality rate was less than what is expected in a population of patients with refractory ascites
- The need for explantation of the pump, renal dysfunction including electrolyte abnormalities and infections remain concerns
- Future studies should include refinement of patient selection criteria, revised pump and catheter design, and procedural and post-procedural care algorithms including the mandated use of albumin

## DISCLOSURES

**FW:** Consultant for Gore, Inc. and Mallinckrodt Pharmaceuticals; grant/research support from Sequana Medical AG, Mallinckrodt Pharmaceutical & Grifols.  
**RTF:** Grant/research support to CPMC Institution from Sequana Medical AG  
**ZH:** Consultant for W.L. Gore and Associates, C.R. Bard, Boston Scientific; grant/research support: Sequana Medical AG  
**JC:** Sequana Medical AG employee  
**PK:** Consultant for Sequana Medical AG