

Updates on MOSAIC Study

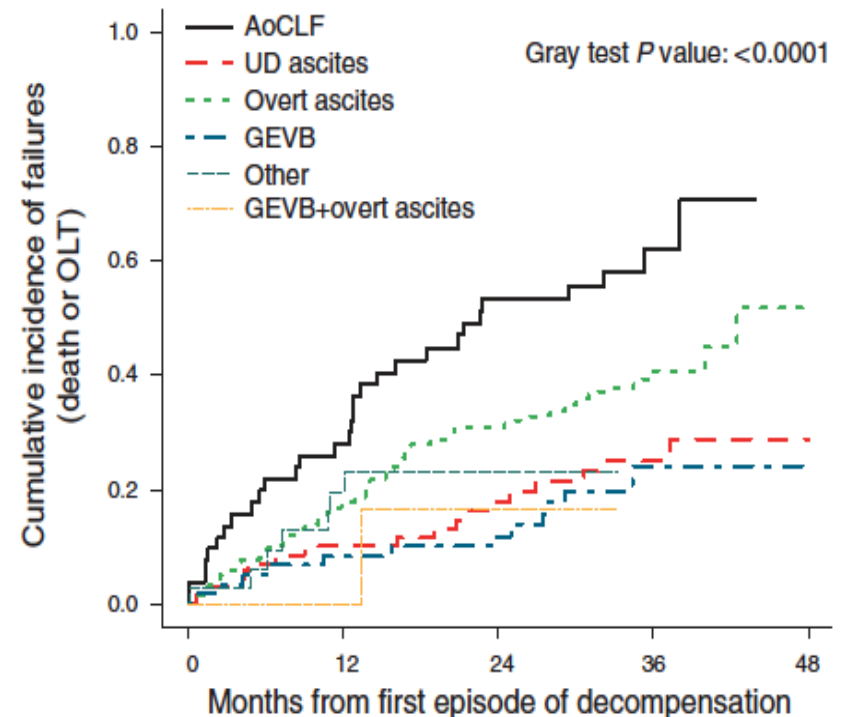
The Toronto Experience

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Poor Survival After Ascites Development



AoCLF	53	33	20	7	
UD ascites	71	60	46	21	2
Overt ascites	230	161	109	25	1
GEVB	60	50	43	11	2
Other*	33	21	13		
GEVB+Overt asc.	8	6	2		

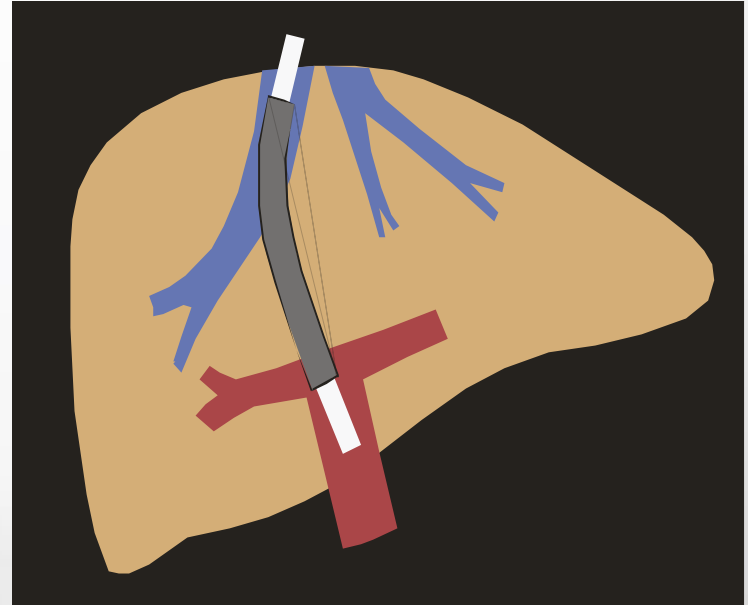


Management of Refractory Ascites



Large volume paracentesis

OR



TIPS

What About Patients Unsuitable for TIPS

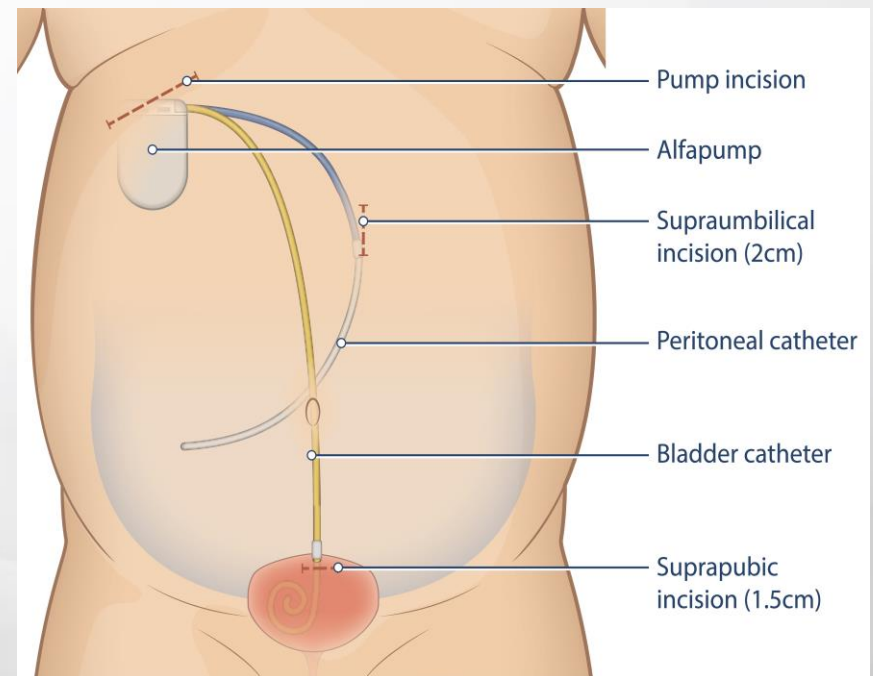
- The >65 years of age
- Patients with prior spontaneous hepatic encephalopathy
- MELD >18
- Portal vein thrombosis
- Pulmonary hypertension
- Heart failure



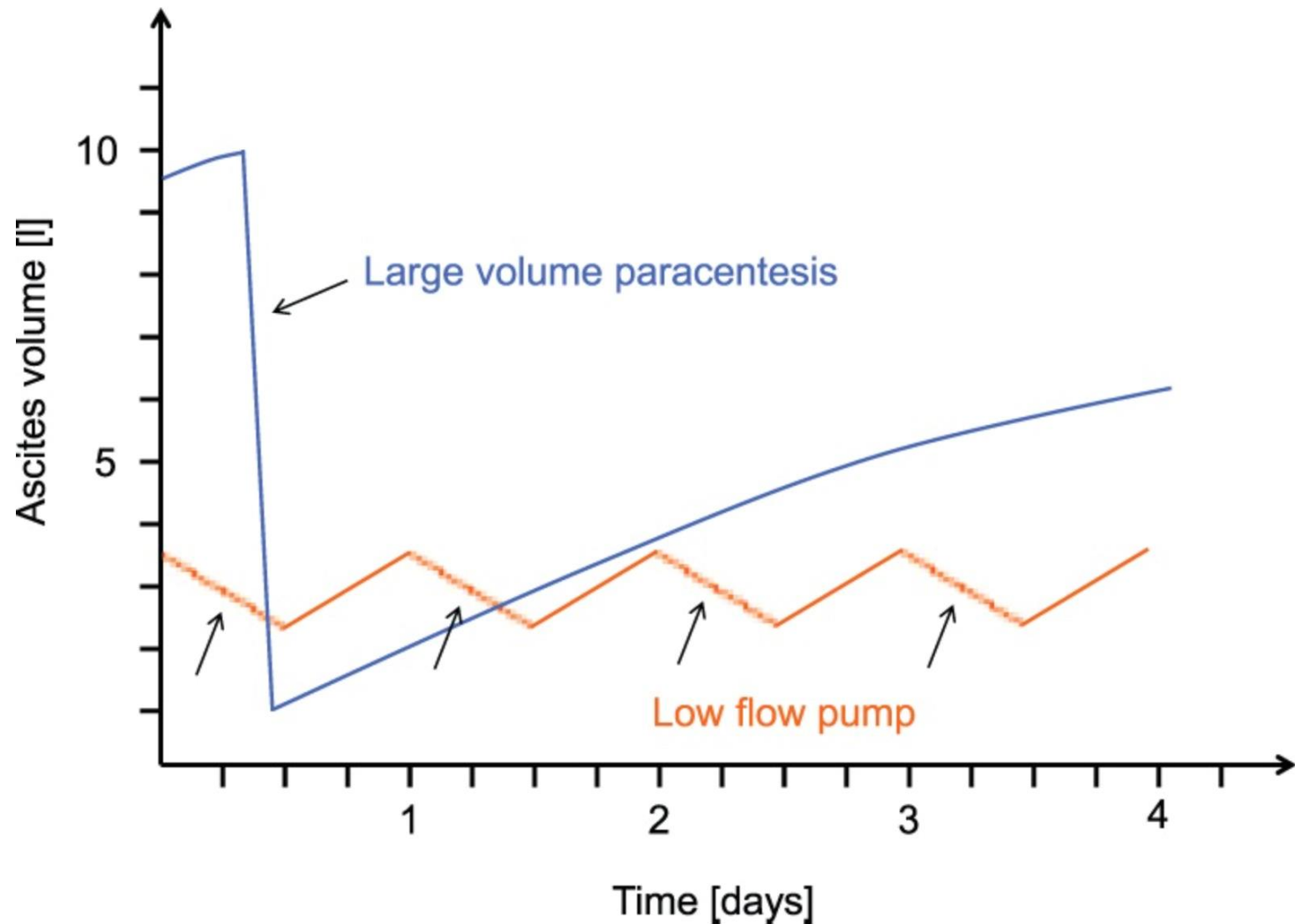
Possible Solution

The **alfapump**® System

Automatically & continually moves ascites from the abdominal cavity to the bladder, where it is excreted naturally from the body.



ALFA pump provides continuous small volume ascites drainage

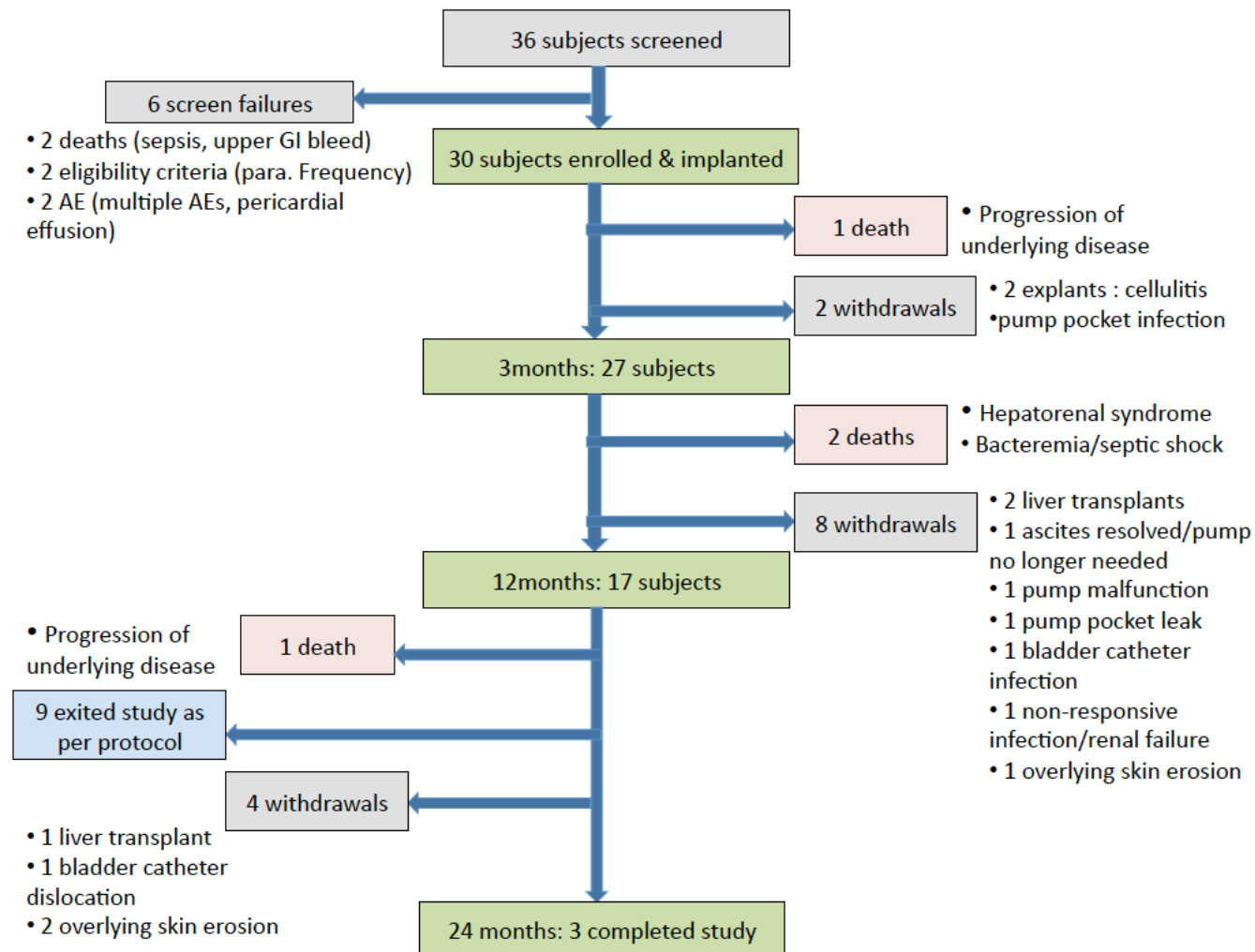


The MOSAIC Study

- First North American prospective, open label, feasibility study
- Assessed the use of alfapump in the management of recurrent or refractory ascites
- Enrolled 30 patients not suitable for TIPS as treatment for ascites from April 2015 to January 2017
- Alfapump inserted by interventional radiological approach in 29/30 patients
- Median follow-up time of 30 patients in North America: 361 days (27-764)



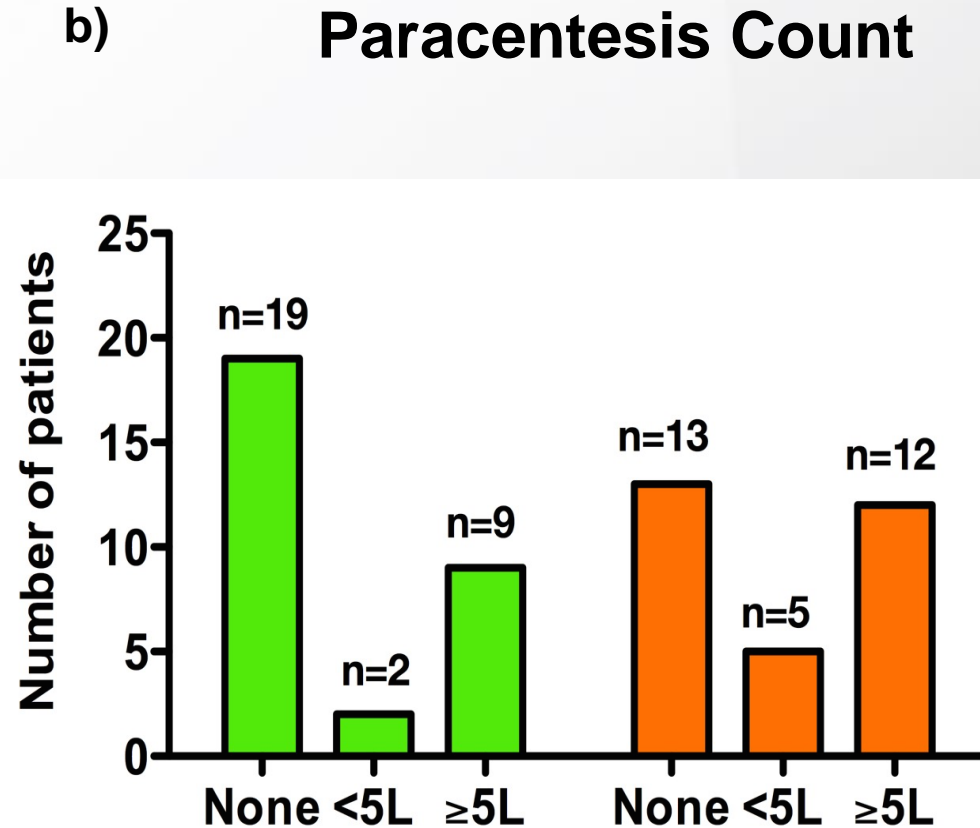
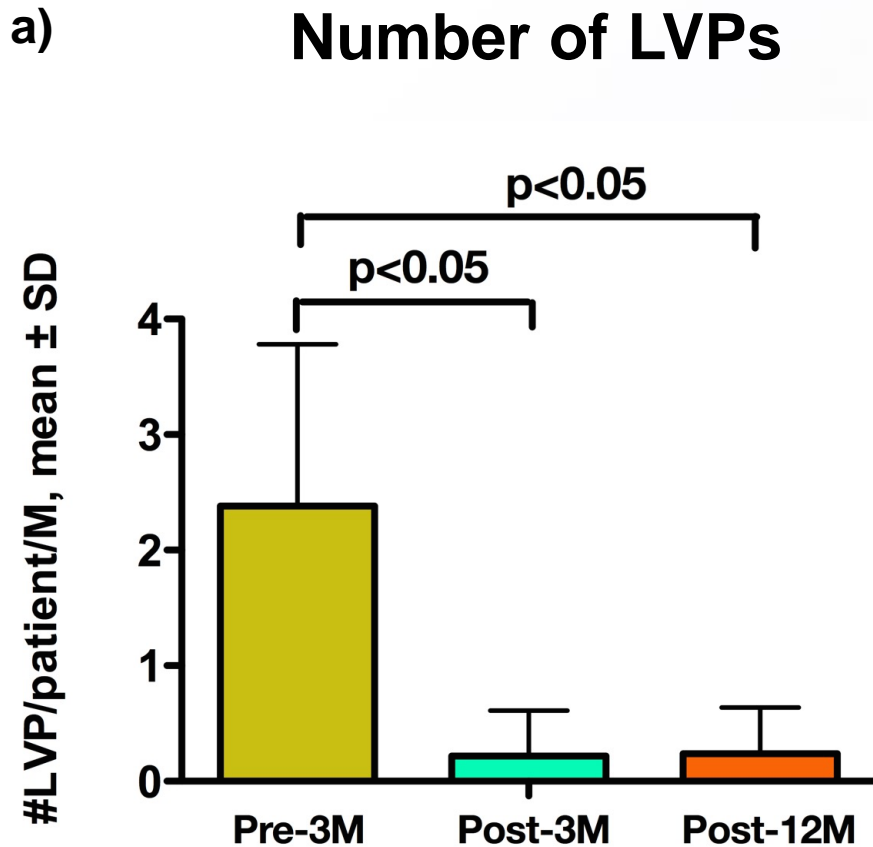
Patient Disposition



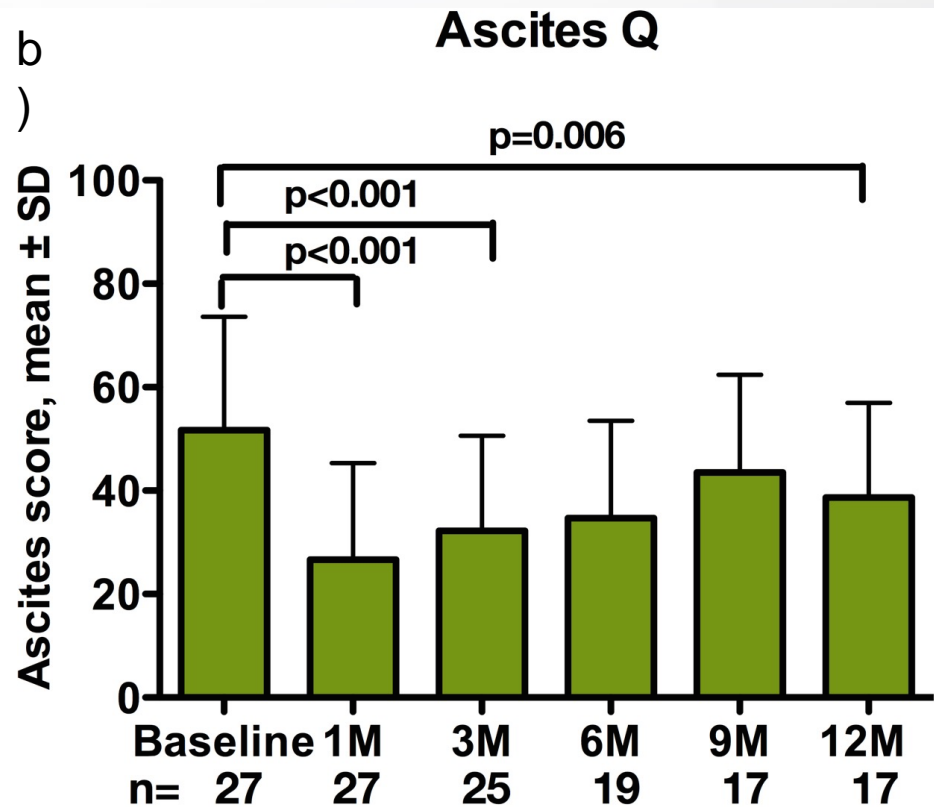
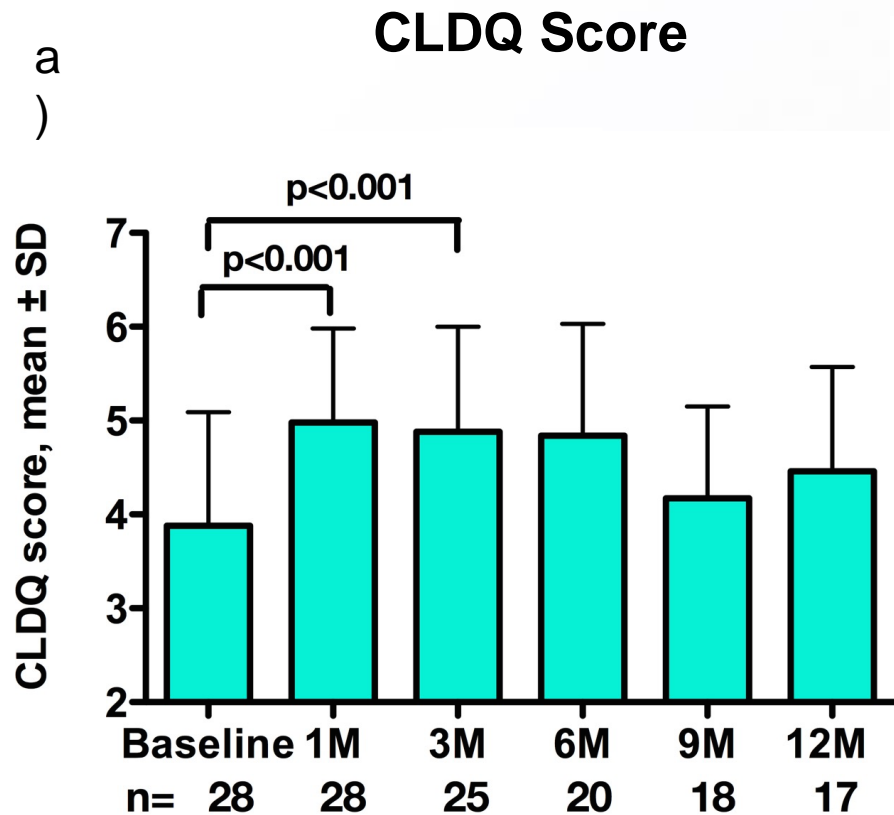
Control of Ascites

- Pump is set to work from 0800-2200 hours
- Average volume per pump cycle: ~6ml
- Average time between pump cycles: 5-6 minutes
- Total ascites removed in 12 months: 317.9 ± 121.9 litres/patient (=53 large volume paracenteses of 5 litres each)
- Average daily ascites volume removed: 883 ± 338 ml

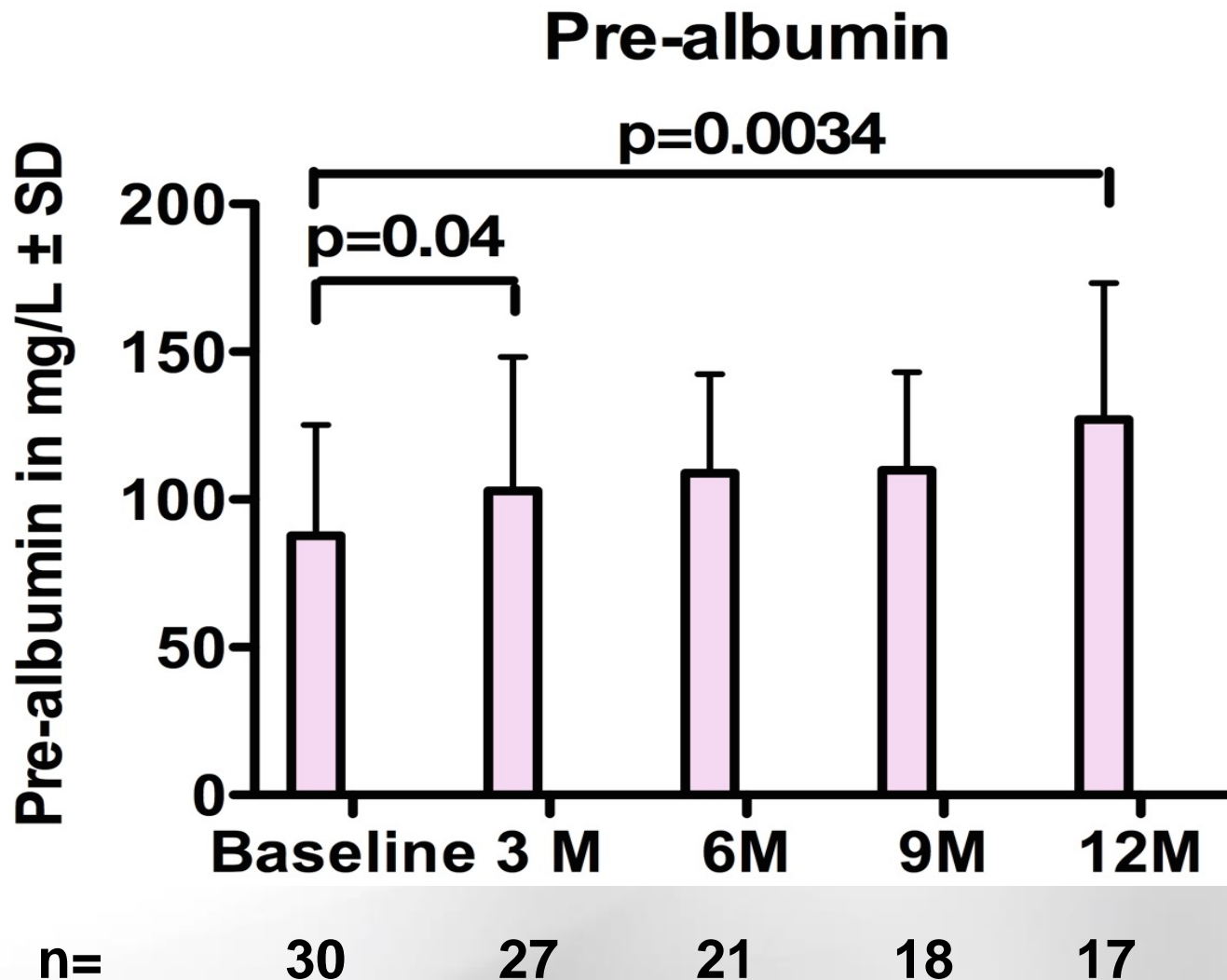
Control of Ascites with alfapump



Quality of Life Changes



Nutritional Status



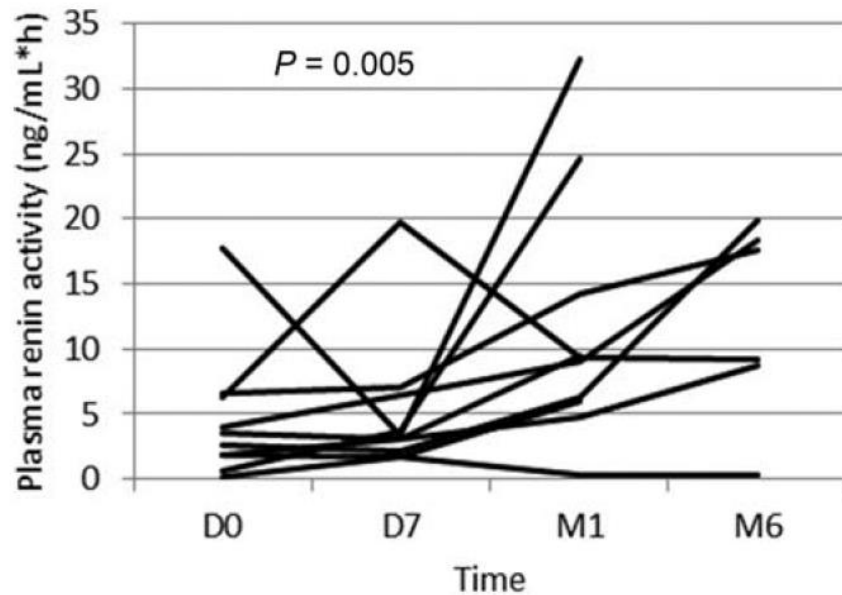
Complications

	3 months		12 months	
Related	# of events	# of events	# of events	# of patients (%)
Total:	12	10/30 (33.3%)	27	13/30 (43.3%)
Post-operative bleeding	1	1/30 (3.3%)	1	1/30 (3.3%)
Leakage of ascites into pump pocket	2	2/30 (6.7%)	2	2/30 (6.7%)
Wound dehiscence	1	1/30 (3.3%)	1	1/30 (3.3%)
Pump malfunction	2	2/30 (6.7%)	4	3/30 (10%)
Bladder catheter malfunction	1	1/30 (3.3%)	3	3/30 (10%)
Peritoneal catheter malfunction	0	0	1	1/30 (3.3%)
Hematuria	1	1/30 (3.3%)	1	1/30 (3.3%)
Infection	3	3/30 (10%)	9	8/30 (26.7%)
Hyponatremia	1	1/30 (3.3%)	2	1/30 (3.3%)
Acute kidney injury	0	0	2	2/30 (6.7%)
Skin erosion over pump	0	0	1	1/30 (6.7%)

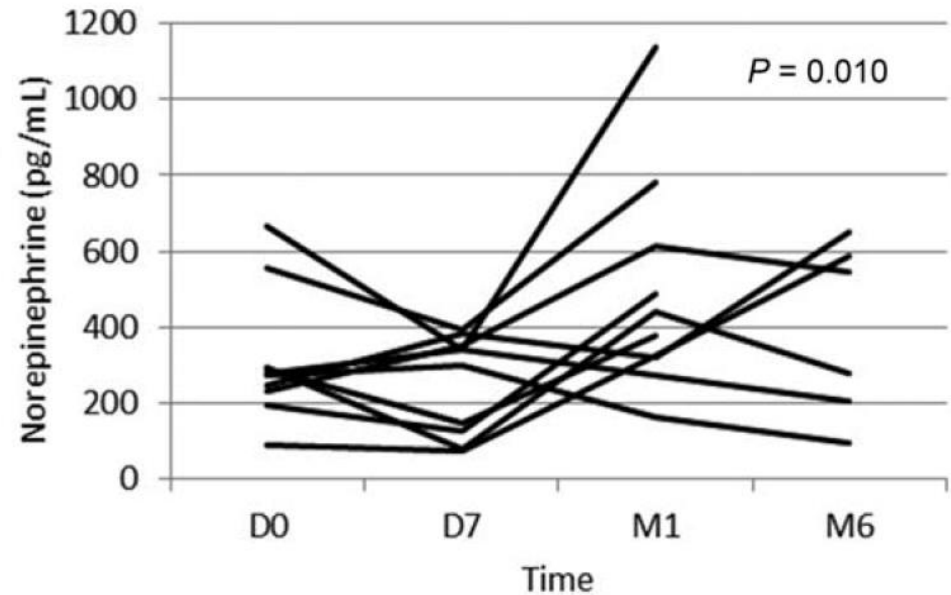


Vasoconstrictor activities post-pump insertion

Plasma renin activity



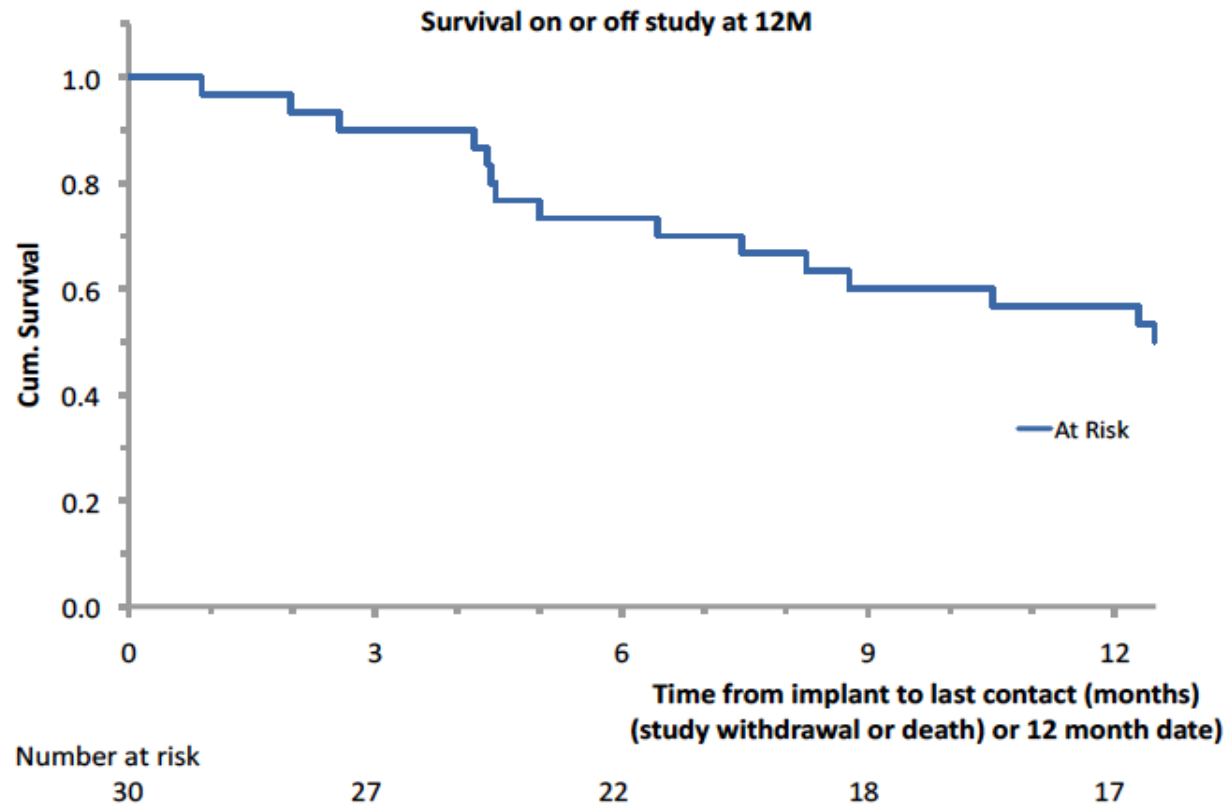
Norepinephrine



Continued monitoring of renal function and intermittent albumin infusions may be required



Survival post-pump insertion



The Toronto Experience

Characteristic	Value
n	15
Age (years)	64±7
M:F	10:5
Etiology of cirrhosis	
alcohol	9
alcohol + viral hepatitis	2
viral hepatitis	1
NASH	1
NASH + viral hepatitis	1
NASH + alcohol	1
Duration of alfapump in situ	23±17 months (Range 4-54 months)
Number of pump(s)/patient	Range : 1-5



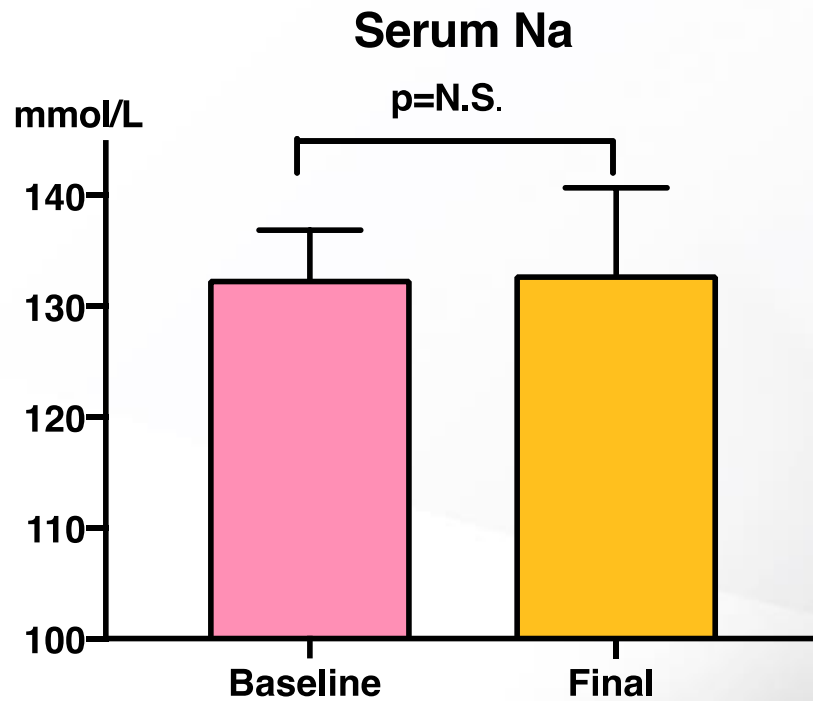
The Toronto Experience

Characteristic	Value
n	15
Mean daily pump volume*	650ml (Range: 200-1100ml)
# pumps explanted	7
Reasons for Explant	
total clearance of ascites	3
worsening of renal function	1
development of HCC	1
Infection	2
Albumin used*	825gm (Range: 0-8750gm)
Total volume of ascites* drained	239.7L (Range : 39.2-1192.0L)

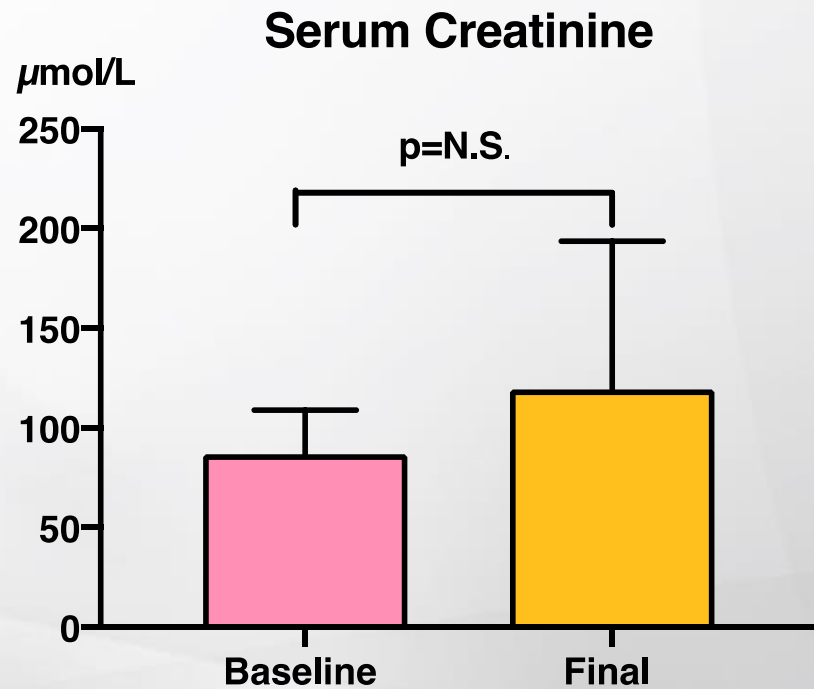
* Median value



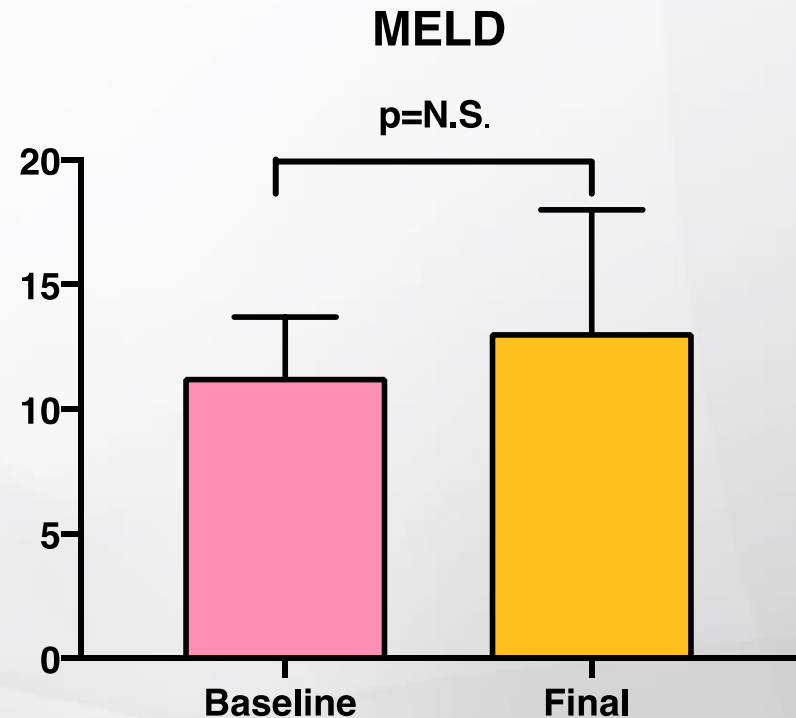
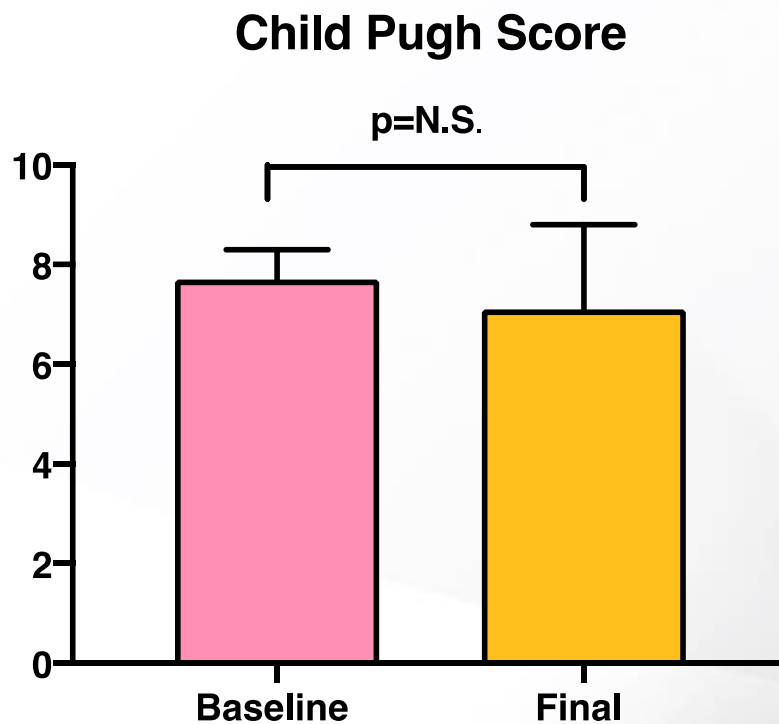
Laboratory Parameters



n=15



Parameters of Liver Function

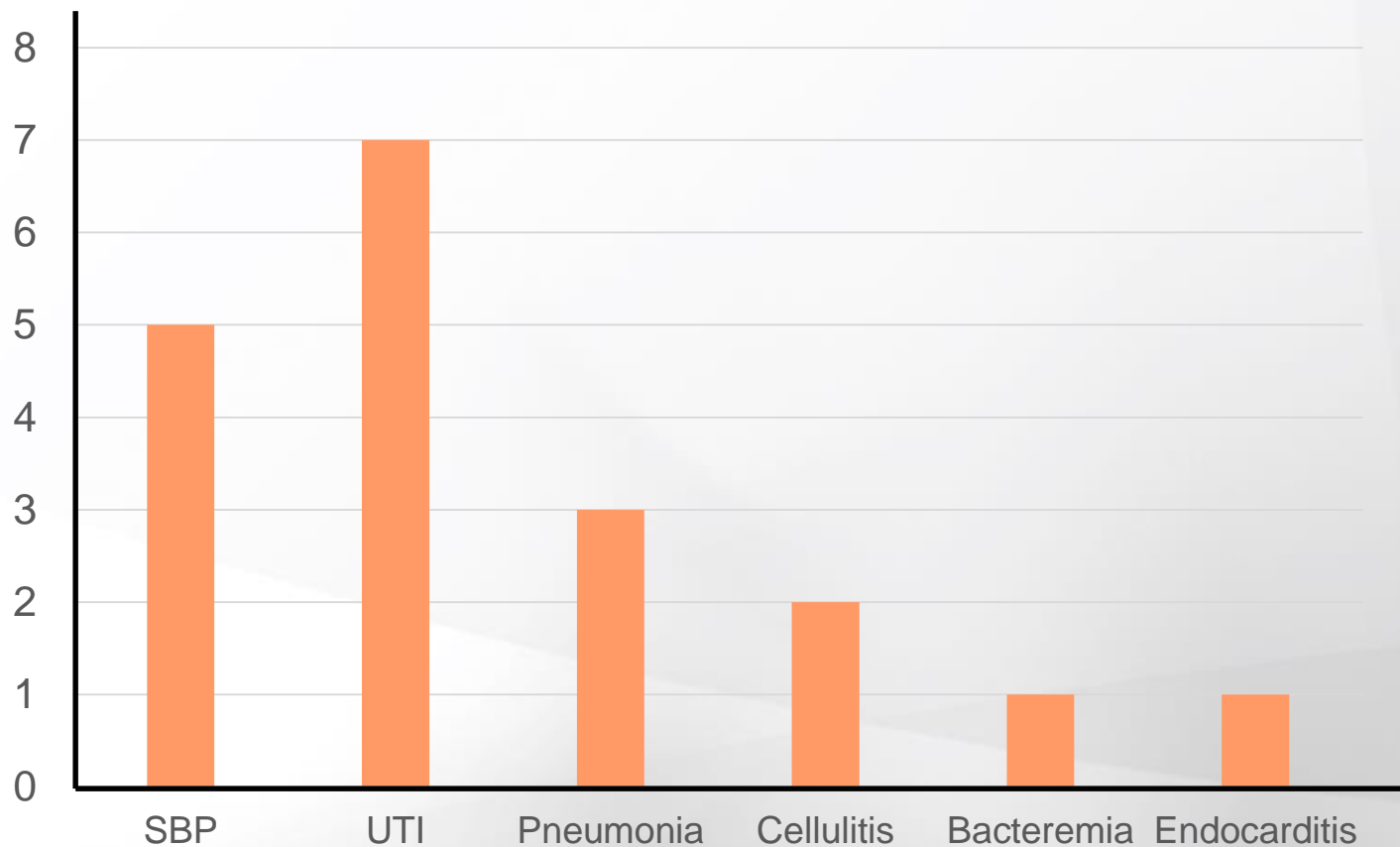


n=15



Major Infections

10/15 patients had major infections



Summary

- Overall experience is positive, especially from patient perspective
- No significant changes in liver or renal function
- May need individualized albumin support
- Bacterial infections, whether related or not related to alfapump are still present in significant number of patients
- Careful patient selection is important
- There is improvement in quality of life and nutritional status with alfapump use, and potential for longer survival

