



Extracorporeal Interstitial Fluid Removal

ICD-10 Coordination and Maintenance Committee Meeting
September 10, 2024

The AquaPass System is intended to treat Fluid Overload in patients with Heart Failure (HF) & Chronic Kidney Disease (CKD)

STRUCTURE

- Founded in 2019
- Strong Team:
 - 11 technical, clinical, quality control and regulatory experts
 - 7 KOLs, Nephrology & Cardiology

CLINICAL, IP, TECHNOLOGY

- Clinical Proof of Concept with 300 treatments on >40 fluid overloaded patients (HF & CKD stages I-V).
Results demonstrate safety, ease of use, comfort and efficacy
- Strong IP¹ position with 2 granted patents & 5 PCT² applications filed with a leading US firm
- Confirmed technology & system design

REGULATORY, QA, GTM

- Granted 2 FDA Breakthrough Designations for congestive heart failure (CHF) & end stage renal disease (ESRD)
- ISO 13485 Certified
- Regulatory path: Confirmed IDE³ study by the FDA, towards a De Novo Pathway

Clinical Need

Heart Failure (HF) and Chronic Kidney Disease (CKD)

Persistent volume overload and congestion are the markers of HF and CKD

- 35.5 million people have kidney disease.
- About 808,000 Americans are living with kidney failure.
- More than 557,000 Americans are on dialysis.
- 6.5 million people in the US have congestive heart failure.
- Leading cause of hospitalization in people older than 65
- >1 million hospitalizations per year for fluid overload

Fluid overload patients suffer from:

Accumulation of excess fluids in the interstitial compartment leading to:

- Recurrent hospitalizations & frequent readmissions post discharge
- Marked reduction in the quality of life
- High mortality rates in the months & years following hospitalization
- Dependency of current therapies on Renal Function in CKD patients
- Current therapies cause worsening renal function, electrolyte imbalance & hypotension
- Patients develop resistance to current therapies

— USING THE SKIN AS A “THIRD KIDNEY”

Our skin has 2-4 million eccrine glands that release interstitial fluid containing water, electrolytes, toxins, heavy metals and urea.

Activation of Perspiration

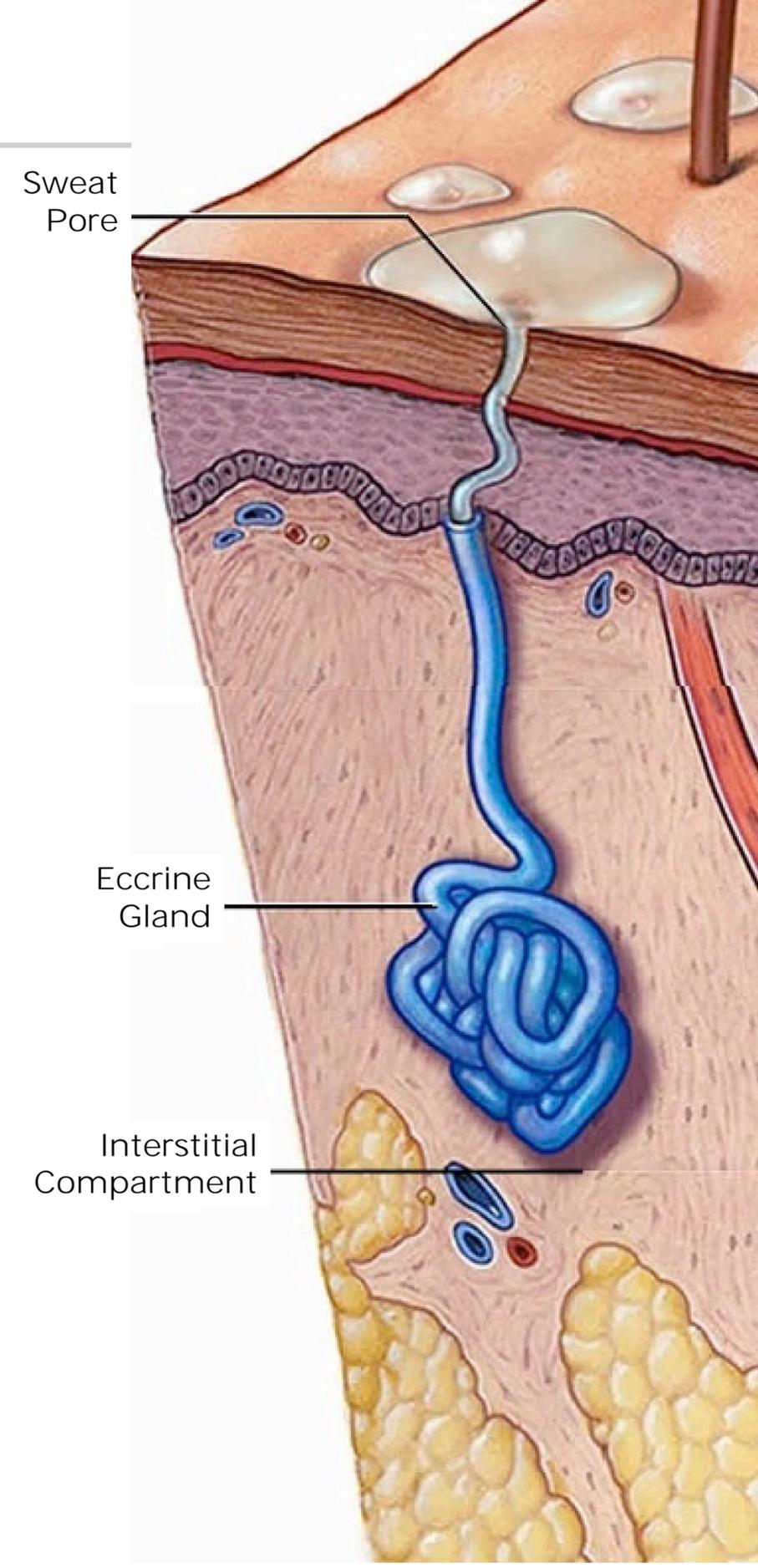
Warming the skin activates the eccrine glands, alleviating fluid overload at clinically meaningful rates

A Renal-Independent Solution

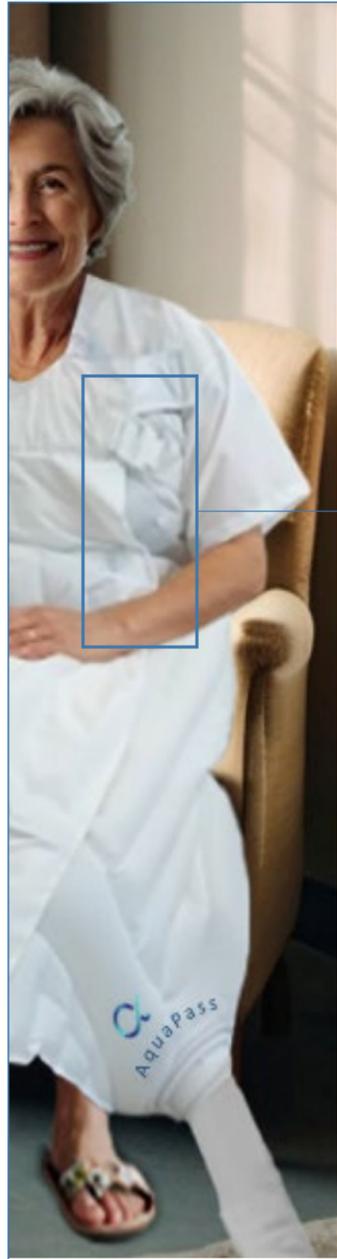
First technology to remove fluid without relying upon or negatively affecting renal function

Staying Cool and Comfortable

Evaporation of fluid during treatment cools the skin, keeping the body temperature normal and the patient dry and comfortable



AQUAPASS SYSTEM COMPONENTS



The system warms and dries air. Sensors that measure the air humidity, temperature and flow at the inlet and the outlet enable optimal, per patient, control of the fluid removal rate

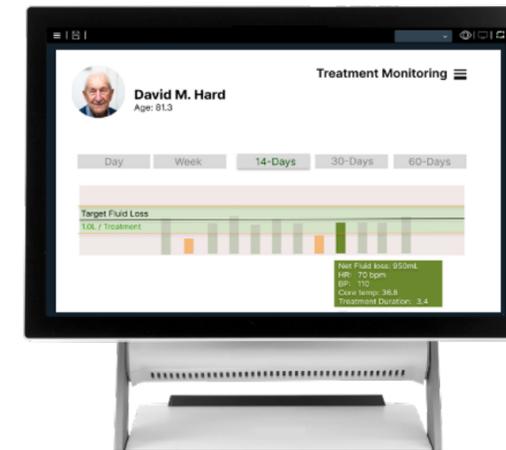


The garment creates the ideal and uniform microclimate for activation of the eccrine glands and will include integrated sensors for continuous patient monitoring.



Patient: treatment app and progress update *

* Expected in Q4-2025



Healthcare provider: remote monitoring station

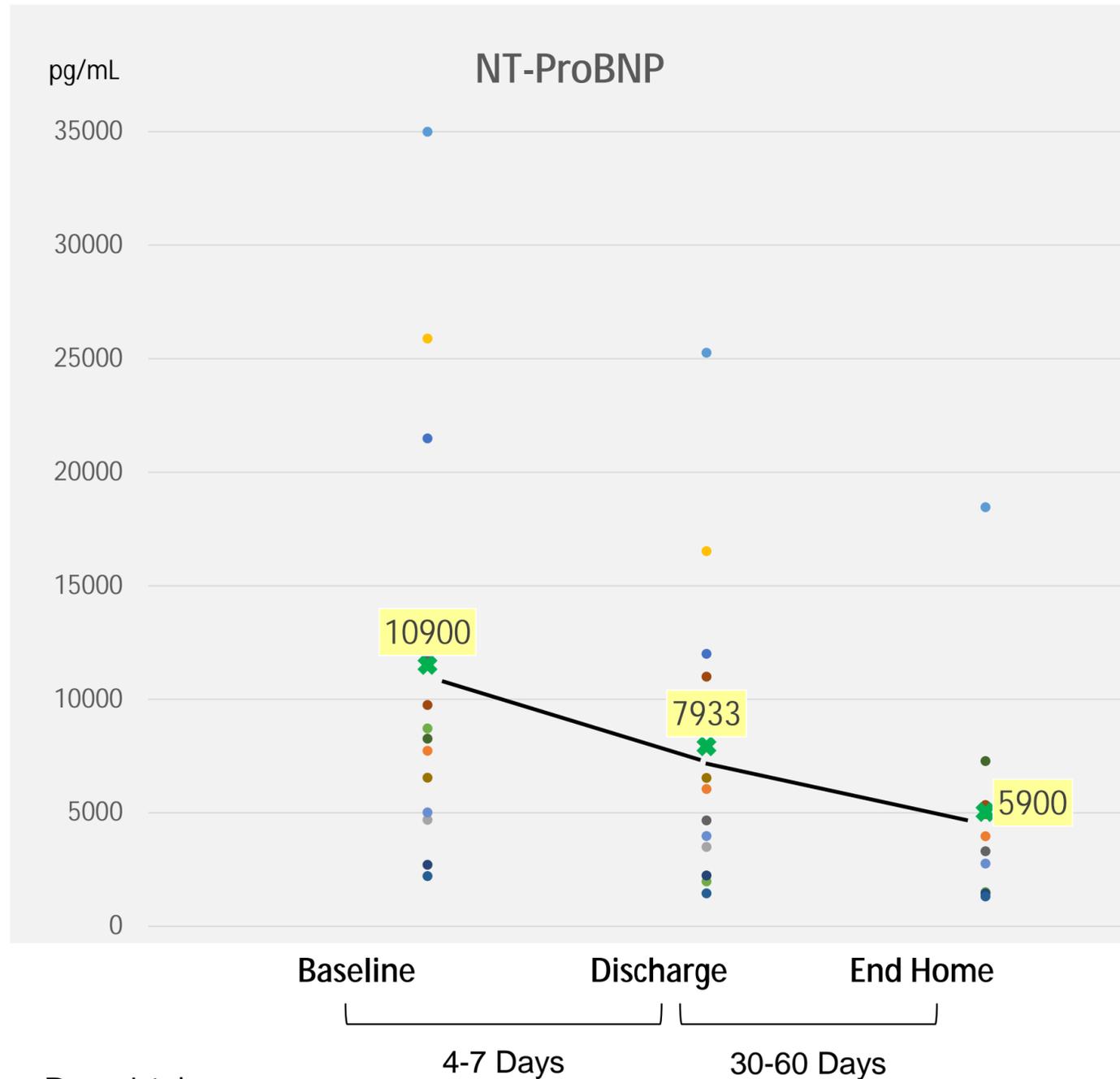
- 300 treatments in 40 fluid overloaded patients: ADHF, CHF & CKD STAGES I-IV
- Safe, comfortable and well tolerated procedures performed in the hospital and at home
- Stable hemodynamics, blood counts and core temperature

Meaningful fluid removal rates >850ml per 4-hour procedure independent of renal function

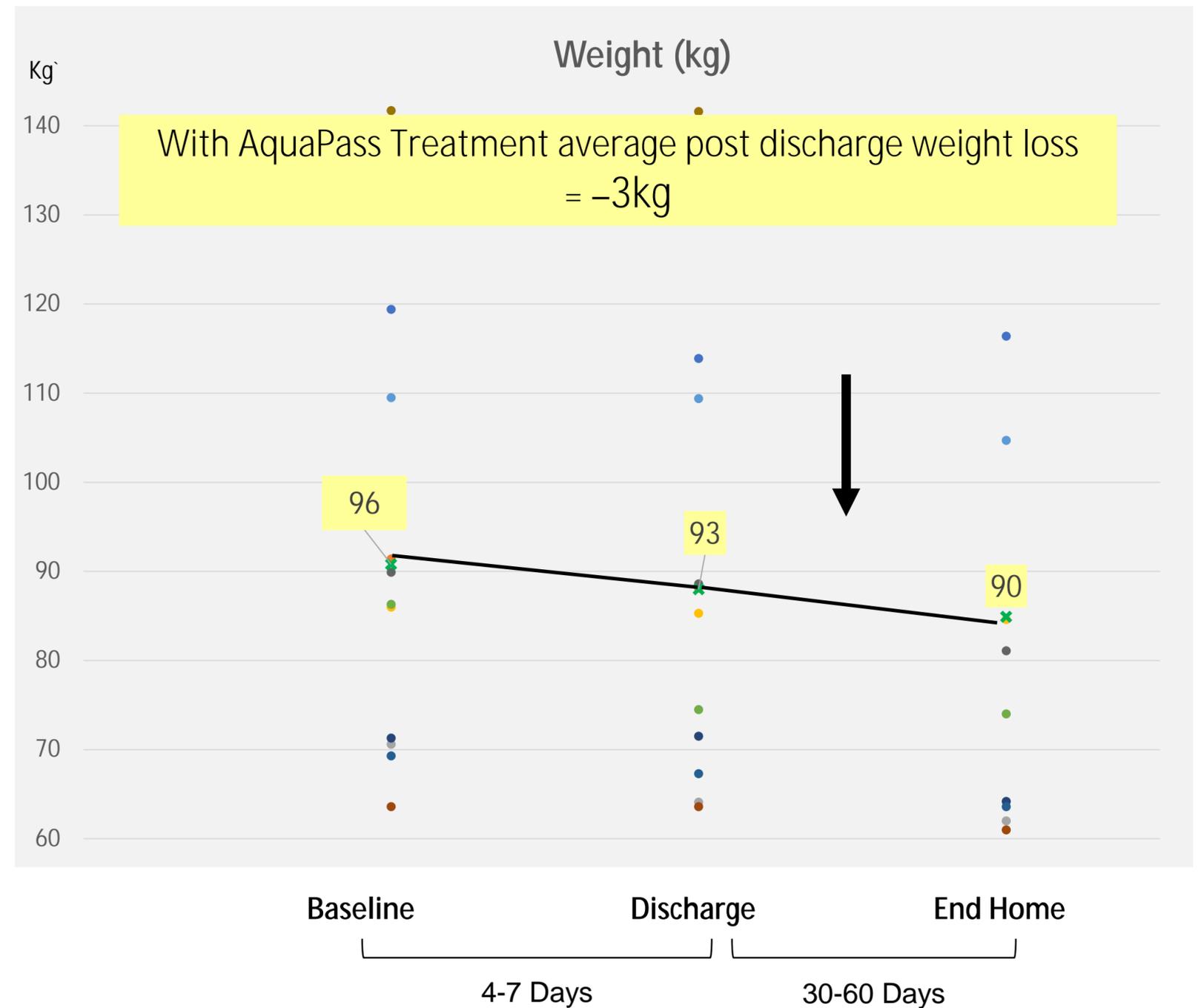
In the Acute Decompensated Heart Failure (ADHF) study, a dramatic improvement from baseline to end of the study in:

- N-terminal pro b-type natriuretic peptide (NT-ProBNP): Reduced on average by **44%**
- Quality of Life Kansas City Cardiomyopathy Questionnaire (KCCQ-12) score: **>46%** Improvement (from 14.6 to 61)
- Congestion score: Reduced on average from **6.2 to 2.1**
- Weight Loss: Average loss of **5.8 kg**
- **0%** 180 Day Mortality
- **0%** 30-Day Heart Failure hospitalizations
- Reduction in diuretics by **28%** (Furosemide or equivalent) during home phase

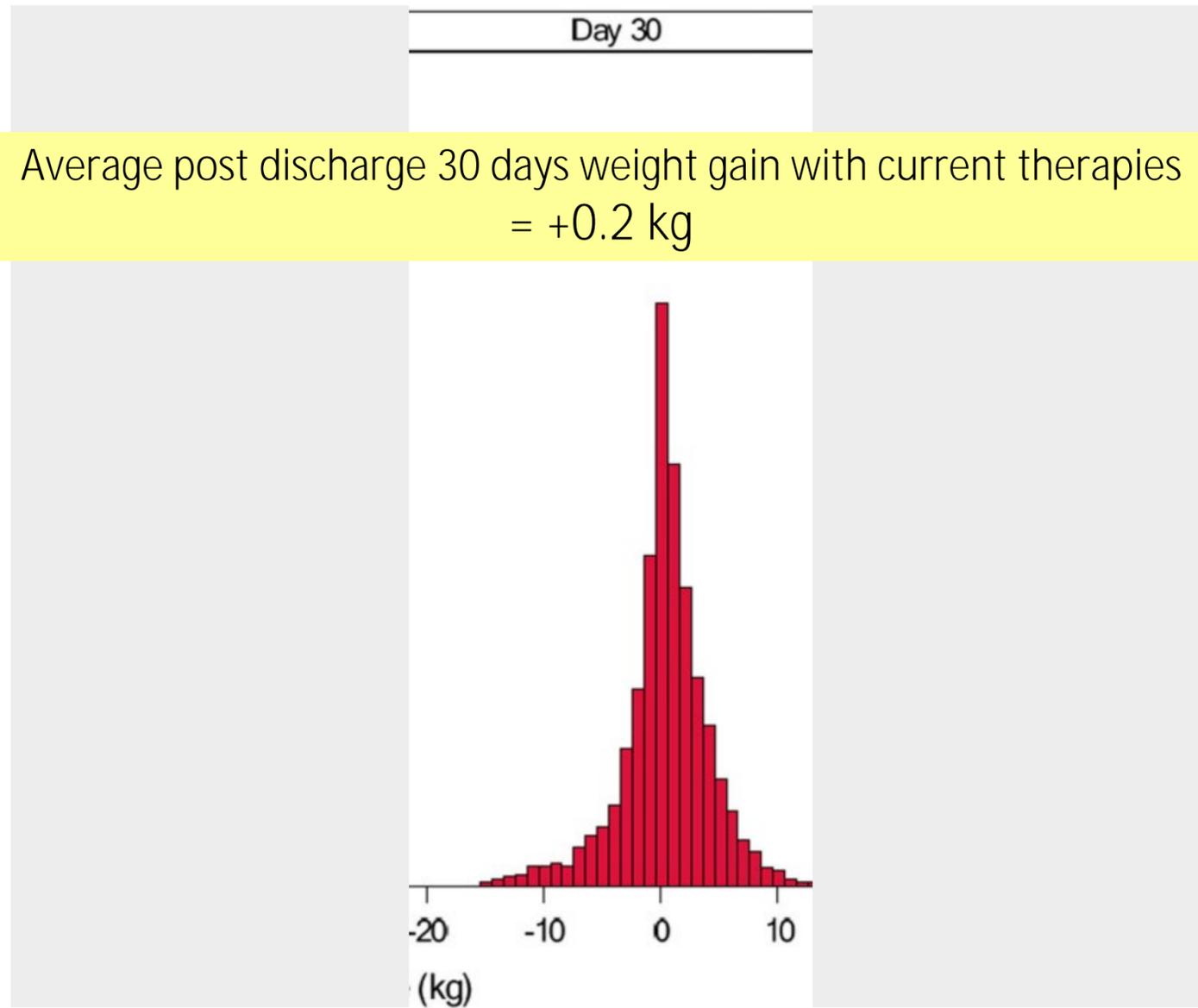
44% REDUCTION IN NT-ProBNP



MEANINGFUL FLUID & WEIGHT LOSS AT HOME

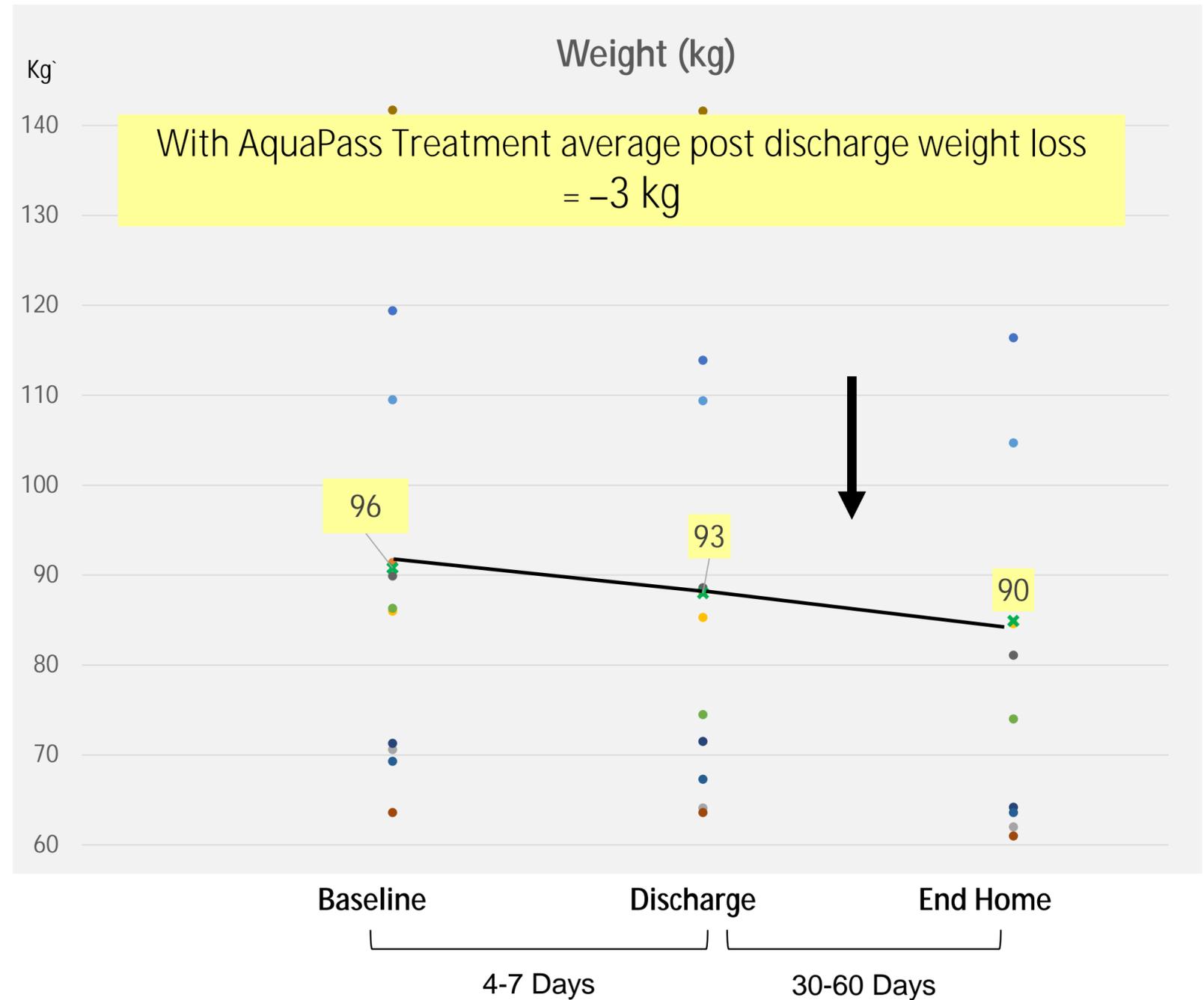


CURRENT THERAPIES WEIGHT GAIN POST DISCHARGE



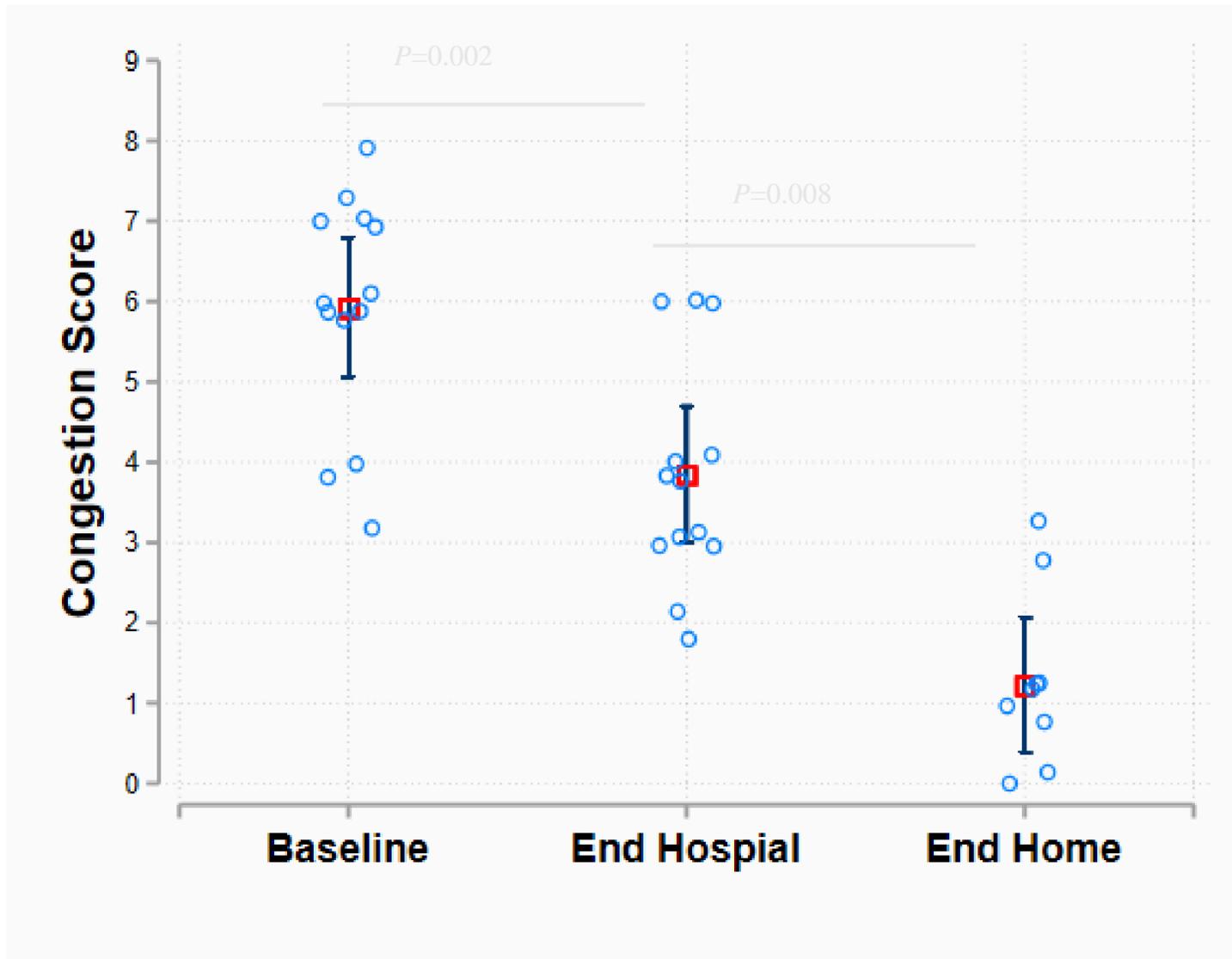
Ambrosy A, JACC 2017

MEANINGFUL FLUID & WEIGHT LOSS AT HOME



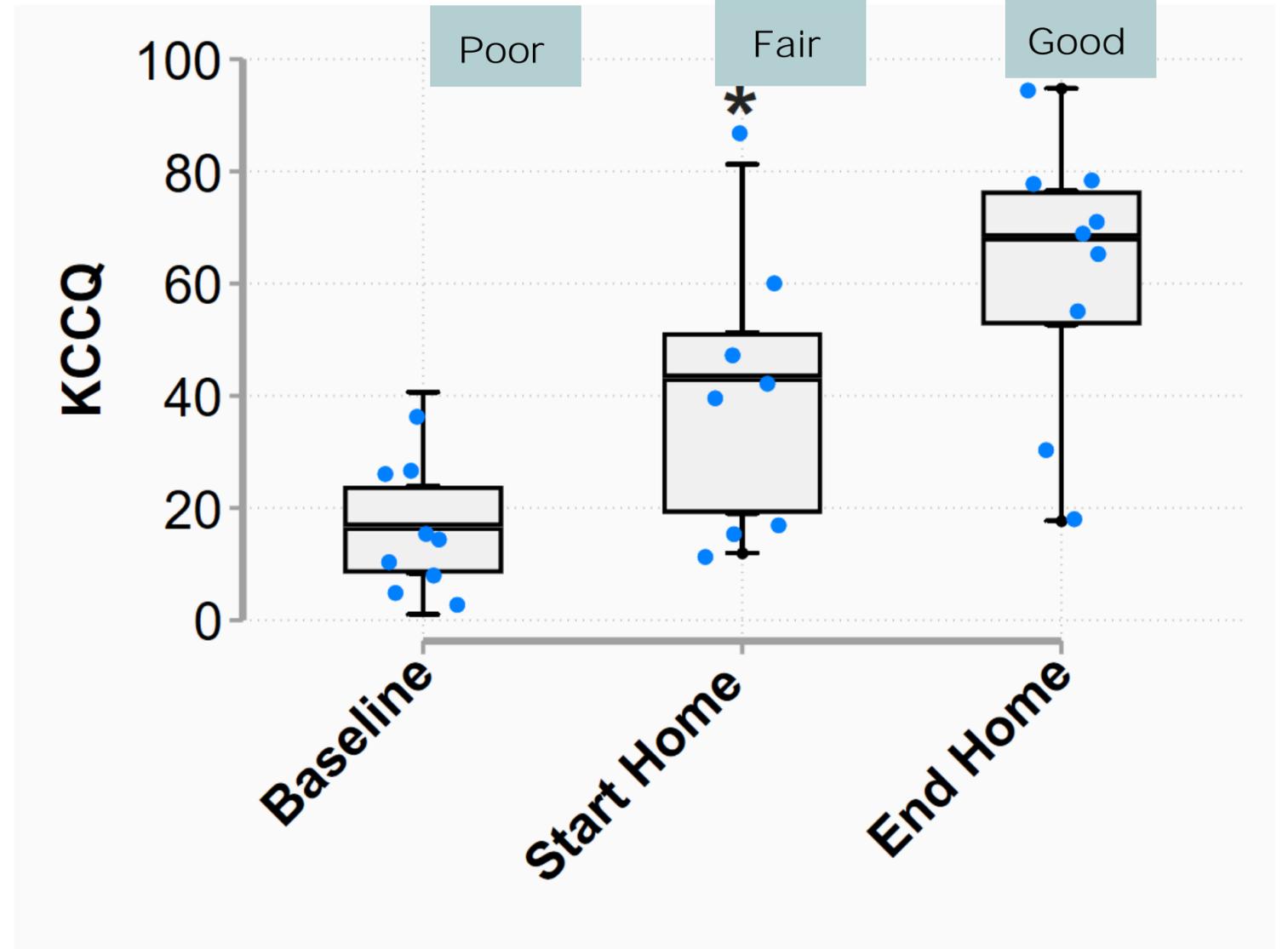
IMPROVEMENT IN CONGESTION

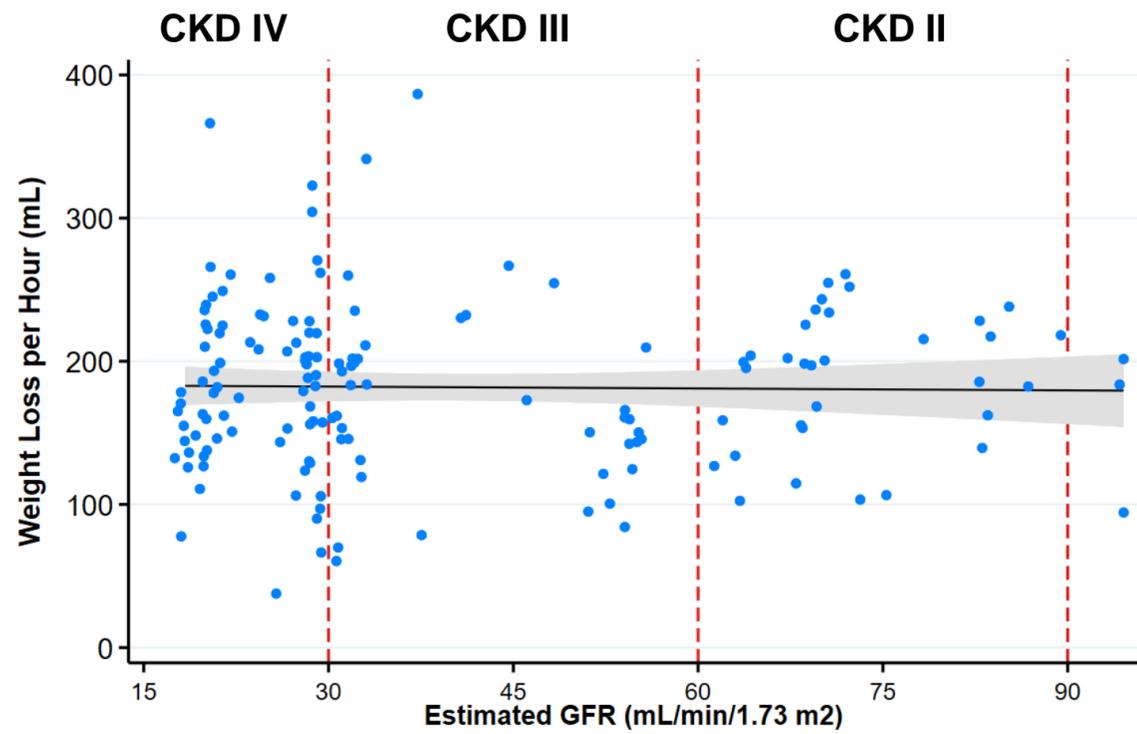
Congestion Score



IMPROVEMENT IN QUALITY OF LIFE (QoL)

QoL: Kansas City Questionnaire





Interdialytic Pilot data in ESRD

Patient	Time Point	AquaPass Fluid Removal, (Kg)	Weight (Kg)	Interdialytic Weight Gain (Kg)	Na+ (mmol/L)	K+ (mmol/L)	BUN (mg/dl)
1. Male, (No urine output)	Observation period		93.3kg	2.7	141	5.6	62
	Following AquaPass treatment	2.3kg	91kg	1.1	142	5.3	49
2. Female, (No urine output)	Observation period		74.6kg	3.8	139	5.84	67
	Following AquaPass treatment	2.2kg	70.3kg	1.75	140	5.1	46
3. Female, (Negligible urine output)	Observation period		79.6kg	2.1	131	5.5	47
	Following AquaPass treatment	1.8kg	77.7kg	1.35	134	5.6	44
4. Female, (Negligible urine output)	Observation period		92Kg	2.2	142	5.6	67
	Following AquaPass treatment	2kg	90.8Kg	0.8	140	5.7	70

Interdialytic Patients

- Significant decrease in interdialytic weight gain
- Stable electrolytes
- Not requiring higher ultrafiltration rates at subsequent dialysis visits

The AquaPass System is an inpatient hospital-based treatment

- Physician's order for, and use of, the AquaPass System will be documented in the daily progress notes of the patient's medical record

Medical Terminology

- The AquaPass System
- AquaPass
- Microclimate Garment

In the ADHF Study, no serious adverse events, sequelae, or complications were associated with the AquaPass System.

*There is an extremely slight risk of burn, and a slight potential for overheating.



THANK YOU

www.aquapass-medical.com
