Evidence Table

Clinical Area: **Ultrafiltration for acute decompensated heart failure.**
Reference: **Costanzo MR, Saltzberg M, O'sollivan J, et al. early ultrafiltration in patients with decompensated heart failure. And diuretic resistance. *J Am Coll Cardiol* 2005;46:2047-2051.**

Study Type: Case series.
Study Aim: To determine if ultrafiltration before intravenous diuretics in patients with decompensated heart failure and diuretic resistance results in euvolemia and early discharge without hypotension or worsening renal function.

Outcomes

Primary: Length of hospital stay and readmission.

Design

- *Number of subjects:* N= 20
- *Description of study population:* These were adult patients hospitalized with CHF in the participating hospitals. Their mean age was 74.5 years (range 50-85 years), 75% were men, and 95% White. Heart failure was ischemic in 75%. LVEF ranged from 10 to 65% with a mean of 31%, 80% had edema, 98% ascites, and 65% had pulmonary rales.
- *Inclusion criteria:* Men and women hospitalized for CHF for $\leq$12 hours, and given no vasoactive drugs, and $\leq$ 1dose of IV diuretic, with renal insufficiency or diuretic resistance, and fluid overload (defined as $\geq$ 2 of the following: 1. at least 2+ peripheral or sacral edema, 2. enlarged liver or ascites, 3. pulmonary rales, paroxysmal nocturnal dyspnea or orthopnea, and 4. jugular venous distension $\geq$7 cm.
- *Exclusion criteria*: Systolic blood pressure <85 mmHg, hematocrit $\geq$ 40%, end-stage renal disease requiring dialysis, hypercoagulability, requirement for intravenous inotropes, or participation in another research study or previously in this trial.
- *Consecutive patients?* No.
- *Exposure/Intervention:* After screening and undergoing required lab tests, heparin was administered and ultrafiltration instituted at a maximum rate of 500 cc/h. The rate was reduced to 200 cc/h if the systolic blood pressure dropped to $\leq$ 80 mm Hg, and stopped when the acute decompensation HF symptoms were resolved.
- *Source of outcome data (e.g. patient self-report, doctor report, lab results):* Physical exams and blood chemistries at baseline, 2 and 24 hours, weights, complete blood count, blood chemistry, and clinical exams were performed daily during hospitalization, and at 30 and 90 days.
- *Length of follow-up:* 90 days
- *Completeness of follow-up:* Not discussed.

Validity

- *Is the study type appropriate for the question(s) being asked?* No, a randomized controlled trial comparing the treatment to an alternative therapy would be more appropriate.
- *Were patients similar with respect to baseline characteristics?* Yes.
- *Was the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)?* Yes.
- *Was the process of observation likely to affect the outcome?* Not for the outcomes with objective measures.
- *Did an objective observer assess outcomes and were outcome measurements consistent?* Yes.
- *Was follow-up duration appropriate?* No not for determining long- term efficacy.

Conclusions regarding validity of methods:

This is a small case series that lacked a control or comparison group.

Results:

- Utrafiltration was started within 4.7 $\pm$ 3.5 hours of hospitalization, and 8,654 $\pm$ 4,205 ml of fluid was removed.
- Average hospital stay was 3.7 $\pm$ 1.8 days. (12 patients (60%) were discharged in $\leq$ 3 days, 20% at day 4, 15% at day 5, and one (5%) at day 10.
- Weight decrease from 87 $\pm$ 23 kg to 81 $\pm$ 22 kg at discharge, 84 $\pm$ 21 at 30 days, and 80 $\pm$ 18 at 90 days (p=0.006 for difference between baseline and after 90days)
- Median BNP at pre-UF=1,230 , at discharge=788, at 30 days=815 (p for difference=0.03)
- Difference in serum creatinine level from baseline to 90 days was not significant.
- Difference in creatinine clearance from pre-UF to 90 days was not significant.

Clinical signs and symptoms of volume overload pre-UF, and at follow-up

Clinical signs and symptoms	*Pre UF*	*At discharge*	*30 days*	*90 days*	*P value*
Peripheral edema	16 (80%)	13 (65%)	12 (63%)	7 (35%)	0.008
Ascites	19 (95%)	15 (75%)	8 (40%)	9 (45%)	0.002
Pulmonary rales	13 (65%)	6 (30%)	1 (5%)	4 (20%)	0.021
*PND**	15 (75%)	8 (40%)	3 (15%)	4 (20%)	0.006
Jugular vein. Distension	19 (95%)	17 (85%)	13 (65%)	6 (30%)	0.0005
Sacral edema	7 (35%)	8 (40%)	1 (55%)	0 (0%)	0.031

* Paroxysmal nocturnal dyspnea

Medications used pre-UF, at discharge, and after 90 days

	Pre-UF	At discharge	At 90 days
	%	%	%
Loop diuretics	75	100	95
Thiazide diuretics	20	30	25
ACE inhibitors	45	45	55
ARBs	0.5	10	15
Beta blockers	50	55	60
Nitrates	40	35	45
Digoxin	35	35	30

P=NS for each of the drugs used.

Authors' Conclusions:

The authors concluded that early ultrafiltration for CHF patients with volume overload and diuretic resistance is safe and effective in reducing congestion and length of hospital stay. They noted that the clinical benefits lasted for at least three months.

Reviewer's Conclusions:

This study was a small case series with no control or comparison group. Case series provide the lowest grade of evidence and are subject to bias. The observed results indicate that the patients underwent an aggressive removal of fluid that resulted in a mean decrease of 6 kg of weight at discharge, and improvement in the clinical signs of symptoms of fluid overload that seems to have lasted for the 90 days of follow-up. The treatment was not compared to an alternative therapy.

The study was supported by the manufacturer of the device CHF Solutions, Brooklyn Park, Minnesota.