HEART FAILURE NETWORK

Randomized Trial of Ultrafiltration versus Pharmacologic Care in Patients with Acute Decompensated Heart Failure and Cardiorenal Syndrome: **Cardiorenal Rescue Study in Acute Decompensated Heart Failure (CARRESS-HF)**

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on behalf of the
NHLBI Heart Failure Clinical Research Network

U.S. Department of Health and Human Services
National Institutes of Health

National Heart Lung and Blood Institute
People Science Health

Background

- Relief of congestion is an important treatment goal in patients with acute decompensated heart failure (ADHF)
- Acute (type 1) cardiorenal syndrome occurs in 25% to 33% of such patients coincident with increasing doses of loop diuretics
- Venovenous ultrafiltration (UF) is a potential therapy in this setting, but little is known about the safety and efficacy of UF compared to pharmacologic care in ADHF complicated by acute cardiorenal syndrome and persistent congestion

Aim

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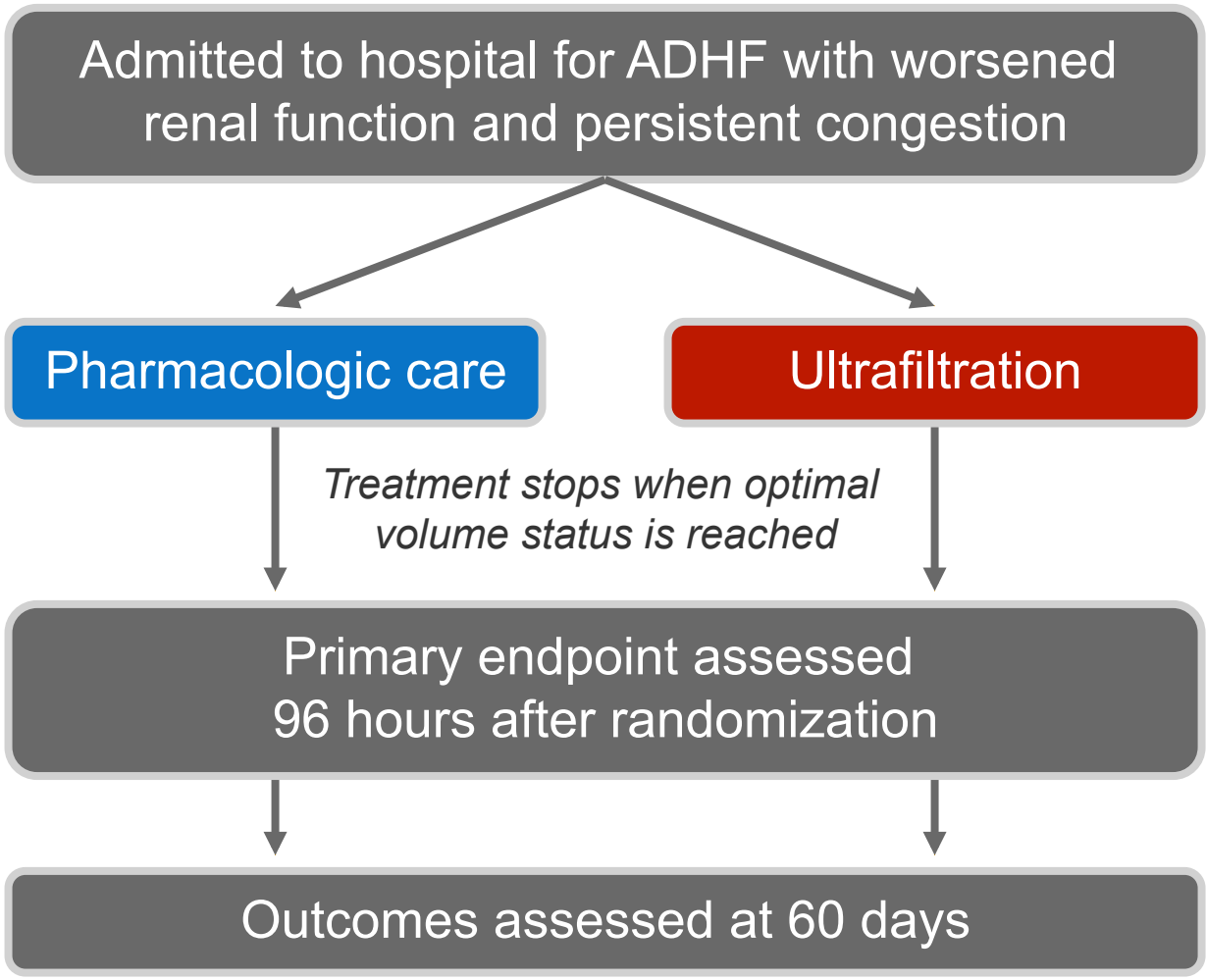
To compare the effects of **ultrafiltration** with **stepped pharmacologic care** algorithm on renal function and weight loss in patients hospitalized with ADHF, worsened renal function, and persistent congestion

Study Design



Patient Selection

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Inclusion

- Age 18 or older
- Admitted to hospital with ADHF
- Worsened renal function with increase in creatinine ≥ 0.3 mg/dL
- Persistent congestion

Exclusion

- Creatinine > 3.5 mg/dL
- Alternate explanation for worsening renal function
- Systolic blood pressure < 90 mm Hg
- Hematocrit > 45%
- Need for IV vasoactive drugs

Randomized Treatment Arms

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Ultrafiltration

- IV access
- Stop all diuretics for duration of UF
- Heparin for PTT 2.0–2.5 x normal
- UF rate 200 mL/hr
- Use of IV inotropes or vasodilators prohibited

Randomized Treatment Arms

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Stepped Pharmacologic Care

First 2 days

- Adjust diuretics to maintain 3–5 liters urine/day

After 48 hours if urine output still inadequate

- Consider dopamine or dobutamine if SBP < 110 mm Hg and EF < 40%
- Nitroglycerin or nesiritide if SBP > 120 and severe symptoms

After 72 hours if urine output still inadequate

- Consider hemodynamic guided IV therapy, crossover to UF, or dialysis

Primary Endpoint

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Change in serum creatinine AND change in weight between randomization and 96 hours, considered as a bivariate response

- Intention to treat
- Multivariate linear regression model, adjusting for baseline values of weight and creatinine

Baseline Features

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Characteristic	Pharmacologic Care (N = 94)	Ultrafiltration (N = 94)
Age — years	66	69
Male	72%	78%
White race	71%	72%
Ejection fraction	35%	30%
HF hospitalization in past year	79%	75%
Ischemic etiology	51%	70%*
Diabetes mellitus	67%	65%
H.O. hypertension	84%	85%
Serum creatinine — mg/dL	2.09	1.90
Qualifying creatinine inc — mg/dL	0.46	0.43

p-value < 0.05

Results: Primary Endpoint

Mean changes in creatinine and weight at 96 hours

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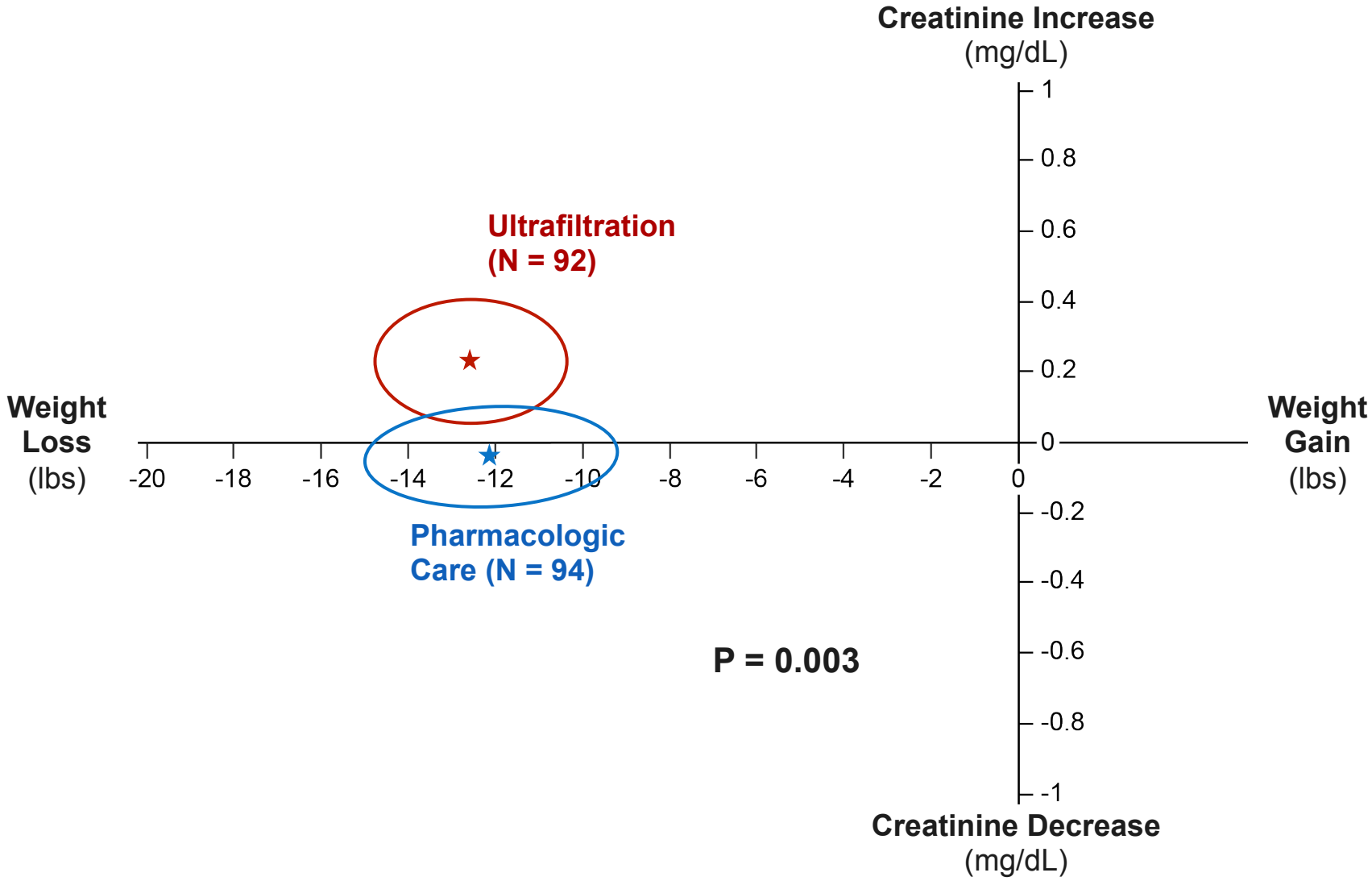
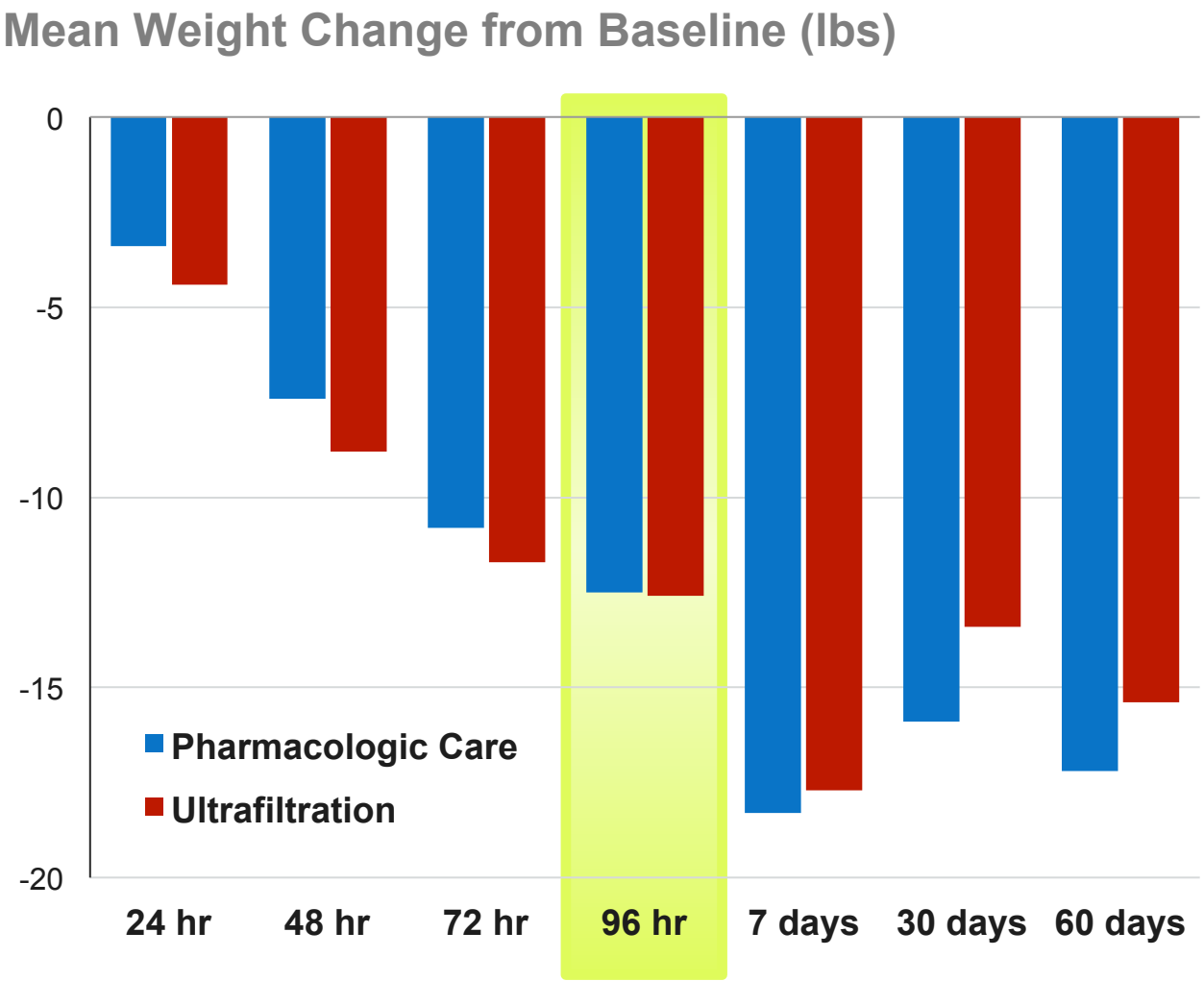


Change in Weight



Change in Creatinine

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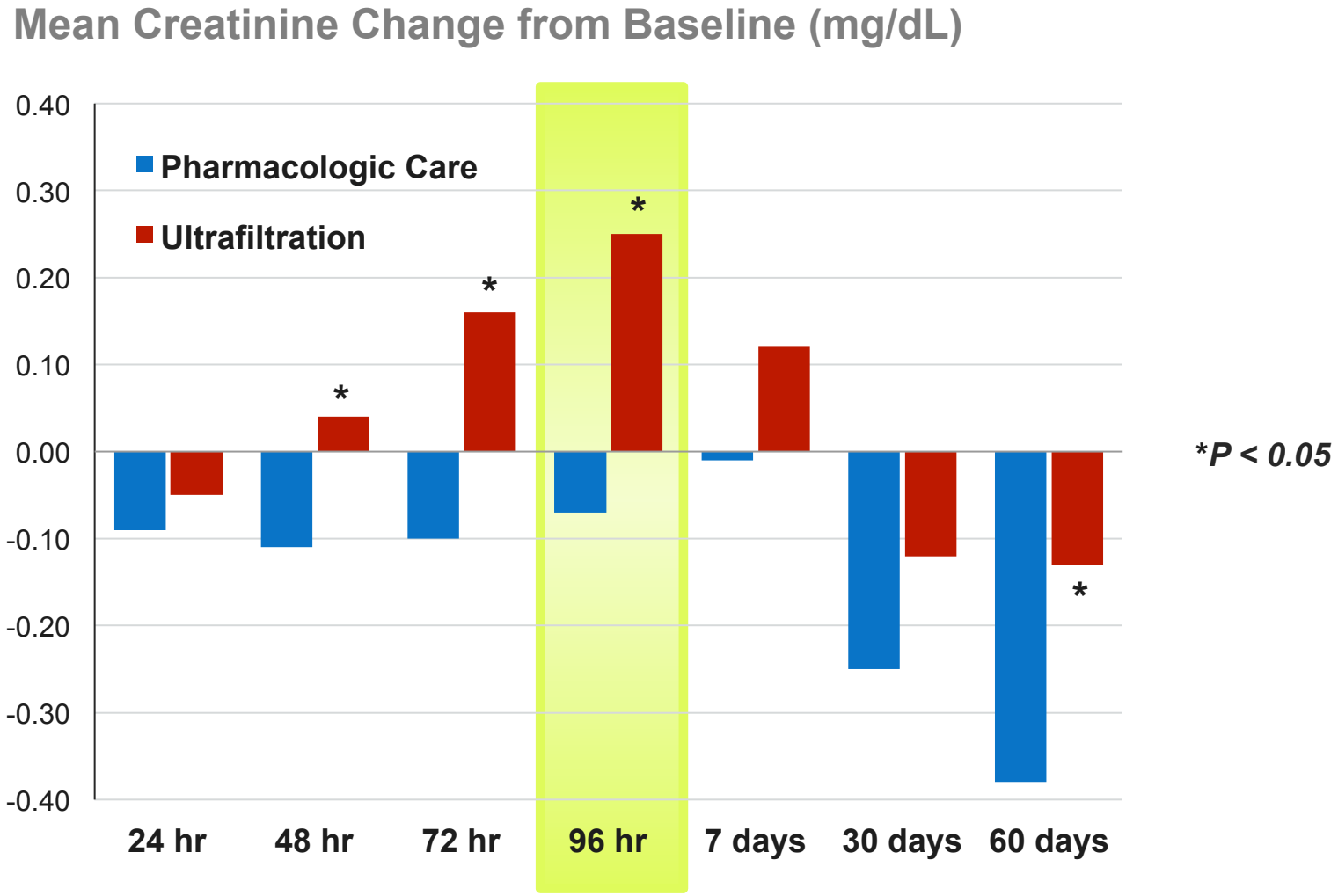

60-day Event Rates

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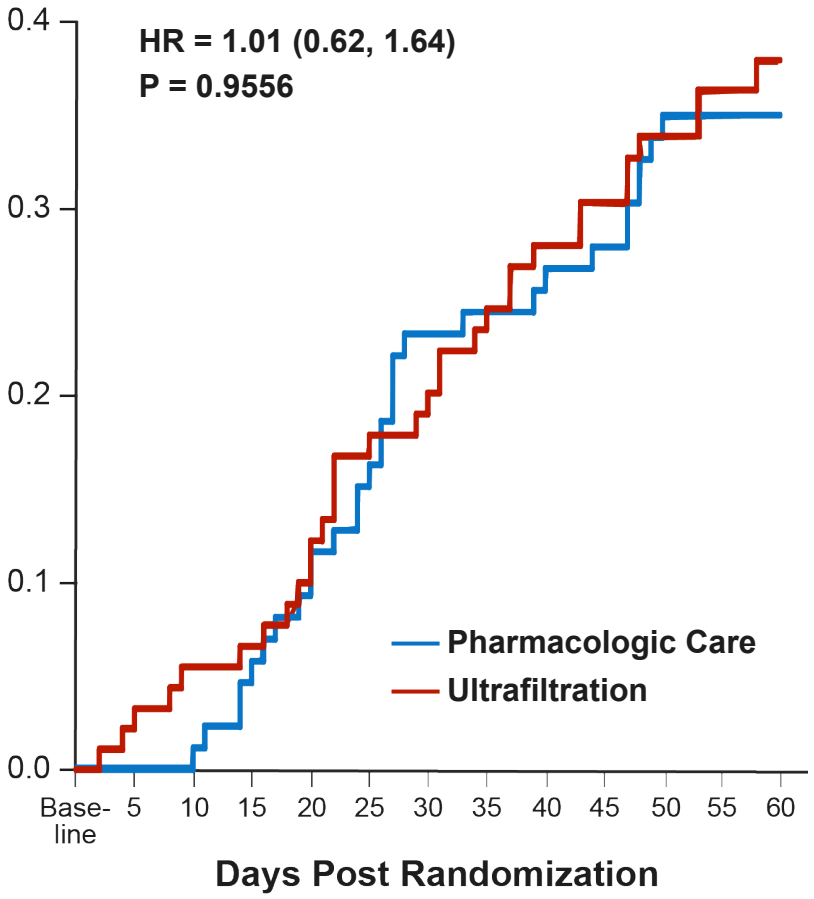
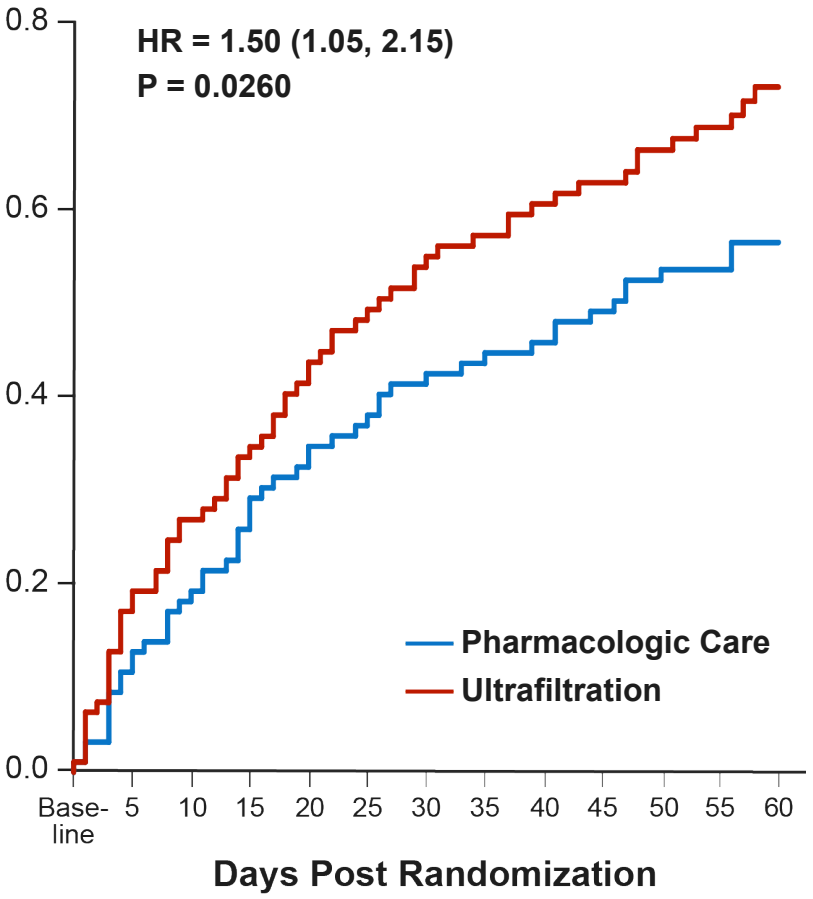
Death or HF Rehospitalization



Death or Serious Adverse Event



Conclusions

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- Pharmacologic care was superior to ultrafiltration at 96 hours for preservation of renal function with similar weight loss
- Ultrafiltration, as administered in this study, had higher rates of adverse events and therefore offers no advantage to stepped pharmacologic care in patients with ADHF, worsened renal function, and persistent congestion
- Treatment of these patients remains a challenging clinical problem in need of better therapy

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