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Restriction therapy in acute heart failure is not shown to be effective

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Restriction therapy in acute heart failure is not shown to be effective

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ABSTRACT A critical appraisal and clinical application of Travers B, O'Loughlin C, Murphy NF, et al. Fluid restriction in the management of decompensated heart failure: no impact on time to clinical stability. *J Card Fail*. 2007;13(2):128-132. doi: 10.1016/j.cardfail.2006.10.012

Keywords: heart failure, fluid restriction, salt restriction

Clinical Context

Our patient, a 77 year old male with a past medical history significant for COPD, CHF (EF 40%), diabetes, and hypertension, presents with four days of foot swelling and dyspnea. Mild crackles were noted at the bilateral lung bases, along with bilateral 1+ pitting edema below the knee. A chest X-ray in the emergency room showed prominent pulmonary vasculature, patchy opacification of the right lower lobe, and focal densities in the left lower lobe, suggestive of heart failure and bibasilar atelectasis. The patient's BNP was 2243, which also supported the diagnosis of heart failure. D-dimer and troponins were both negative, ruling out pulmonary embolism and myocardial infarction as causes of his symptoms. The patient was admitted to the floor for exacerbation of heart failure. He was started on bumetanide 1mg IV twice a day. Fluid restriction is a common clinical practice and may even be considered as a standard of care by some. One member of the rounding team had briefly reviewed some research suggesting that this practice may not be an effective therapy. However, the team decided to initiate fluid restriction therapy while the evidence behind this decision was investigated. Over the course of his hospitalization, the patient was diuresing well; however, he was experiencing excessive thirst.

Clinical Question

Is fluid restriction an effective therapy for acute decompensated heart failure?

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Research Article

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Literature Review

We searched for prospective, randomized trials investigating the use of fluid restriction in patients admitted to hospitals for acute heart failure. We started our literature search on PubMed, using the terms "fluid," "restriction," "restricted," "acute," "hospitalized," and "heart failure," in various combinations. We also searched references in review articles or chapters found in *Harrison's Principles of Internal Medicine*[1], Dynamed and UpToDate . We reviewed society guidelines by the American Heart Association/American College of Cardiology Foundation[2] and Heart Failure Society of America[3]. For each trial, references were reviewed to find additional studies that may have been previously missed. Ultimately, we discovered only two trials meeting these criteria.

The Aliti study[4] was a single-blinded, placebo-controlled study of 75 patients, randomized to free fluid group vs. fluid and salt restriction group. As their primary outcome, they performed a "3-day assessment" of weight loss and congestion (via Clinical Congestion Scoring). They found no significant difference. They did find a significant increase in perceived thirst in the restriction group, though this was a secondary outcome. Patients were allocated up to 36 hours after admission. Importantly, the study authors did not mention whether the three-day assessment occurred at three days of admission or three days after allocation. It is possible that the study patients were evaluated after very little exposure to restriction therapy. This is a major flaw that could obliterate any potential effect of restriction therapy.

While the Aliti trial was an otherwise adequate study to investigate, we decided to review the Travers study[5], since it did not have any similar major flaws. The study's patient population also more closely mirrored our patient (mean age in the study was 74, mean EF was 37-40%), while the Aliti trial studied younger patients (mean age of 60) with more severe chronic heart failure (mean EF 26%).

In addition, we found one systematic review and meta-analysis.[6] While it did not specifically address clinical outcomes in decompensated patients such as ours, we did investigate the studies they collected and analyzed. We found no additional studies investigating clinical outcomes in patients with decompensated heart failure.

It is notable that no prospective, randomized trials reported any clinically or statistically significant net benefit for restriction. Both Harrison's and DynaMed did not recommend restriction as part of therapy, nor did the ACCF-AHA guideline. Guidelines from the HFSA recommend salt restriction and mild fluid restriction, but offer no evidence to support this recommendation. UpToDate similarly recommends restriction, but offers no evidence in support of this and acknowledges insufficient data for this recommendation.

Critical Appraisal

This study was a prospective, randomized trial (SORT level 2) of 77 patients admitted to the hospital for heart failure. \Patients were randomized to either free fluid access or one (1) liter per day fluid restriction. The primary outcome was time to clinical stability, defined as symptomatic improvement, stable weight, no need for IV therapies and no change in cardiac medications for 48h. Time to stability was 7.0 days (SD 7.0 days) in the free fluid group, 8.3 days (SD 6.3 days) in the restriction group. This data favors free fluid by 1.3 days, however the effect was not statistically significant (p=0.18). In order to cause one extra day of clinical instability, one would have to treat only 0.8 patients with fluid restriction (number needed to harm 0.8). There were also no statistically significant changes in secondary outcomes, including duration of IV therapy (trend favors fluid restriction by 0.5 days), biochemical markers (Na, Cr, BUN, BNP), total daily fluid output (trend favors fluid restriction by ~350mL) and average weight loss (trend favors free fluid by 0.4kg).

Patients were allocated using a computer-generated protocol. No details of this protocol were disclosed. There were no significant baseline differences between the two treatment groups. Investigators were blinded to patients' allocation. The treatment teams were also blinded to patient allocation, with the exception of the HF nurses. They do not specify what role the HF nurse has within the treatment of the patient. However, it was noted that outcomes were determined by the blinded HF physician and not the HF

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nurse. Patients were not blinded to their allocation. This is a reasonable study design choice, since it would be nearly impossible to truly blind patients to their allocation group.

Four patients (12%) from the free fluid group had to be withdrawn due to creatinine increases, while ten patients (29%) had to be withdrawn from the fluid restricted group. This difference was not significant (p=0.13). This means there is a potential for selection bias in the study. This is a high rate; however, since more patients from the fluid restriction group had to drop out due to clinical worsening, this favors the fluid restriction group because it selects for a subset of patients who were doing less poorly. Combined with the overall trend, this does not invalidate the hypothesis that fluid-restricted patients did not do clinically better than patients with free access to fluid. This also means that their analysis was not truly intention-to-treat, as they have claimed.

The greatest flaw in this study is its size and limited population. It is reasonable for now, since it is the first study of its kind that questioned the use of fluid restriction in acute heart failure. However, it is difficult to reach a strong, definitive conclusion based on the results of this small study.

Clinical Application

In our patient, a 77 year old male admitted to the hospital for acute heart failure, the results of the Travers trial suggest that aggressive fluid and sodium restriction have no significant efficacy. The study is of moderate quality, but is a trial with a small sample from a limited population. It is, however, the best evidence available and there is no evidence of any kind to suggest that such restriction is effective. The Aliti trial also notes that aggressive restriction resulted in a significant increase in perceived thirst, which was noted in our patient. Based on the current literature, our patient's excessive thirst could have been prevented by allowing him free access to fluid and salt. Free access to fluid and salt is unlikely to have affected his clinical course. In a subsequent patient with acute decompensated heart failure, we did not restrict our patient's fluid and sodium intake. Her clinical outcome was similar and she did not have a prolonged length of stay. She did not suffer from thirst and was more amenable to the treatment plan.

Take Home Points:

1.) Fluid and salt restriction in acute heart failure is a common practice that is not supported by any clinical trials. The evidence that is available suggests that it is a practice that is not beneficial with side effects, though more reliable research needs to be done.
2.) Even non-pharmacological therapies may have significant side effects. Such therapies should be demonstrated beneficial if we continue to subject our patients to their side effects.
3.) We often do things based on a simplistic understanding of pathophysiology. However, human pathophysiology is quite complex and our understanding is incomplete. Research and evidence are necessary to understand what is best for our patients.

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