

Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

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Is fluid restriction needed in heart failure?

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Abstract

Fluid restriction is usually recommended in chronic heart failure. However, the evidence base to support this is not that clear. Searching in Epistemonikos database, which is maintained by screening multiple databases, we identified five systematic reviews evaluating 11 studies addressing the question of this article, including seven randomized trials. We extracted data, combined the evidence using meta-analysis and generated a summary of findings table following the GRADE approach. We concluded fluid restriction probably decreases hospital readmission in chronic heart failure and might decrease mortality, but the certainty of the evidence for the latter is low.

Problem

Chronic heart failure is a morbidity that impairs quality of life, requires frequent hospitalization and increases mortality. Many symptoms of heart failure are a consequence of sodium and fluid overload, so it is usually recommended to restrict fluid intake as a way to compensate volume overload. However, this measure might also have negative consequences, such as thirst, orthostatic hypotension and renal failure. It is not clear whether this recommendation is supported by scientific evidence.

Methods

We used Epistemonikos database, which is maintained by screening multiple databases, to identify systematic reviews and their included primary studies. With this information, we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

Key messages

- Fluid restriction probably decreases hospital readmission in chronic heart failure and might decrease mortality.
- It is not clear whether fluid restriction increases thirst because the certainty of the evidence is very low.



About the body of evidence for this question

| What is the evidence. See evidence matrix in Epistemonikos later | We found five systematic reviews [1],[2],[3],[4],[5] including 11 primary studies relevant to the question of this article, reported in 12 references [6], [7],[8],[9],[10],[11],[12],[13],[14],[15], [16], [17], among them seven randomized trials reported in eight references [6],[7],[8],[9],[10],[11],[12],[13]. Two trials evaluated patients with acute heart failure, so they were not considered relevant to the question addressed in this summary [8],[10].This table and the summary in general are based on the five randomized trials evaluating patients with chronic heart failure [6],[7],[9],[11],[12]. | | |
|--|--|--|--|
| What types of patients were included | Four trials evaluated patients with compensated heart failure [6],[7],[9],[12] and one included decompensated patients [11]. Average age in the trials was 71, and most participants were men. | | |
| What types of interventions were included | In two trials, fluid restriction was 1 litre per day [9],[11] and in three was 1.5 litres per day [6],[7],[12]. In three trials, the patients also received sodium restriction [6],[11],[12]. All of the trials compared against placebo or standard treatment. | | |
| What types of outcomes were measured | The different reviews grouped outcomes as follows: Mortality Hospital readmission Thirst Intravenous diuretic needs Serum sodium level Plasmatic creatinine BNP level | | |

Summary of findings

The information on the effects of fluid restriction for chronic heart failure is based on four randomized trials including 678 participants, because one trial did not report any outcome of interest, or did not present it in a way it could be incorporated in a meta-analysis [12]. Four trials reported the outcomes mortality and hospital readmission [6],[7],[9],[11] and three reported thirst [6],[7],[9].

The summary of findings is the following:

- Fluid restriction might decrease mortality in chronic heart failure, but the certainty of the • evidence is low.
- Fluid restriction probably decreases hospital readmission in chronic heart failure. The certainty of the evidence is moderate.
- It is not clear whether fluid restriction increases thirst because the certainty of the evidence is very low.



| Patients Intervention Comparison | Chronic heart failure Fluid restriction No restriction | | | | | |
|--|---|--|-----------------------------|---|--|--|
| Outcomes | Absolute effect* | | | | | |
| | WITHOUT fluid restriction | WITH fluid restriction | Relative effect (95% CI) | Certainty of the evidence (GRADE) | | |
| | Difference: patients per 1000 | | | (| | |
| Mortality | 85 per 1000 | 57 per 1000 | RR 0.67 (0.39 to 1.15) | ⊕⊕OO ^{1,2} Low | | |
| | Difference: 28 pat (Margin of error: 5 | ients less per 1000 52 less to 13 more) | | | | |
| Hospital readmission | 428 per 1000 | 325 per 1000 | | | | |
| | Difference 103 patients less per 1000 (Margin of error: 214 less to 69 more) | | (0.47 to 0.70) | Moderate | | |
| Thirst*** | 4.5** | 4.84 | | 0000133 | | |
| | Difference (MD): 0.34 more (2.07 less to 2.74 more) | | | Very low | | |

RR= Risk ratio.

MD= mean difference.

Margin of error = 95% confidence interval (CI).

GRADE: evidence grades of the GRADE Working Group (see later in this article).

* The risk **WITHOUT fluid restriction** is based on the risk in the control group of the trials. The risk **WITH fluid restriction** (and its margin of error) is calculated from relative effect (and its margin of error).

** Approximated average in the control group across evaluated trials.

*** Thirst evaluated with visual analogue scale, from 0 (no thirst) to 10 (maximal thirst).

 1 We downgraded the certainty of the evidence in one level for risk of bias because most trials have limitations. We did not downgrade for the outcome thirst because bias would reinforce the conclusion.

 2 We downgraded the certainty of the evidence in one level for imprecision because the confidence interval includes the possibility of no effect.

³ We downgraded the certainty of the evidence in two levels for inconsistency of results (I²=90%).

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different⁺ is low.

⊕⊕⊕O

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different[†] is moderate

⊕⊕00

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different⁺ is high.

⊕0000

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different⁺ is very high.

*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'. † Substantially different = a large enough difference that it might affect a decision.



Other considerations for decision-making

To whom this evidence does and does not apply

- The evidence presented in this summary applies to a broad spectrum of patients with chronic heart failure.
- However, the existing evidence does not allow ruling out whether a subgroup benefits from this measure. For instance, renal failure, advanced heart failure, concomitant sodium restriction or use of diuretics.

About the outcomes included in this summary

• The outcomes included in the summary of findings table are those considered critical for decision-making according to the opinion of the authors of this summary. They coincide with those usually reported in the reviews and guidelines analysed.

Balance between benefits and risks, and certainty of the evidence

• Even though the certainty of the evidence is limited, the benefit/risk ratio is favorable.

What would patients and their doctors think about this intervention

- It is a measure usually recommended, with low-cost and probably beneficial, so the vast majority of patients and doctors should be inclined to use it.
- It is important to inform the patient about the existing uncertainty for both benefits and adverse effects.

Resource considerations

• Fluid restriction does not require financial resources. Considering its possible impact on mortality and hospital readmission it would be a cost/effective measure.

Differences between this summary and other sources

- This summary partially agrees with the reviews identified, which conclude that it is a safe intervention, or that the evidence is limited. One of the reviews exclusively focuses on thirst in heart failure [5], and incorporates a more extensive analysis than the presented in this summary, but it also concludes there is important uncertainty.
- This summary partially agrees with the main guidelines, but these put less emphasis on existing uncertainty. For instance, the Heart Failure Association of the European Society of Cardiology guidelines recommends avoiding excessive fluid intake [18], restricting it to 1.5 to 2 litres per day in patients with severe heart failure in order to alleviate congestive symptoms. Fluid restriction based on body weight might cause less thirst (30 cc/kg, 35 cc/kg if more than 85 kg). The Heart Failure Society of America guideline recommends a daily fluid intake <2 L in patients with severe hyponatremia (Na < 130 mEq/L) and suggests to consider it in all patients with volume overload despite high-dose diuretics and sodium restriction [19]. The ACCF/AHA guideline 2013 also recommends fluid restriction [20].</p>

Could this evidence change in the future?

- The probability of new evidence changing the conclusions of this summary is high, due to the existing uncertainty.
- According to the WHO International Clinical Trials Registry Platform, there are at least two ongoing trials that might provide relevant information [21],[22].



How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.

The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.

The rows represent systematic reviews that share at least one primary study, and columns display the studies.

The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the interactive version: Fluid restriction for chronic heart failure

Notes

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here

http://dx.doi.org/10.5867/medwave.2014.06.5997.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decisionmakers with technology. Its main development is Epistemonikos database (<u>www.epistemonikos.org</u>).

These summaries follow a rigorous process of internal peer review.

Conflicts of interest

The authors do not have relevant interests to declare.

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