Ultrafiltration for patients with acute decompensated heart failure: A systematic review and meta-analysis

Meng-jun Wang, MMᵃᵇ, Yan-mei Zheng, BMᵃ, Hong-xu Jin, MDᵃᵃ

**Abstract**

**Background:** Ultrafiltration plays an indispensable role in relieving congestion and fluid retention in patients with acute decompensated heart failure (ADHF) in recent years. So far, there is no consistent agreement about whether early ultrafiltration (UF) is a first-line treatment for patients with ADHF. We, therefore, conducted a meta-analysis to assess the efficacy and safety of UF.

**Methods:** PubMed, Embase, and Cochrane Library databases were searched for randomized controlled trials (RCTs) that compared UF with diuretics in patients with ADHF and included our interested outcomes. The primary outcomes are heart failure rehospitalization, all-cause rehospitalization, and mortality. The second outcomes are fluid loss, weight loss, and adverse events. RevMan Version 5.4.1 was used to analyze the data of included studies.

**Results:** A total of 12 studies with 1197 patients were included. Our results showed a reduction in heart failure rehospitalization (risk ratio [RR] 0.67, 95% confidence interval [CI]: 0.52–0.87; P < .003) and all-cause rehospitalization (RR 0.62, 95% CI: 0.42–0.92; P = .02), an increase in fluid loss (1.47 L, 95% CI: 0.95–1.99 L, P < .001) and weight loss (1.65 kg, 95% CI: 0.90–2.41 kg; P < .001). There was no difference in mortality (RR 1.09, 95% CI: 0.78–1.51; P = .62). There were inconsistent agreements about which group have more total adverse events. Subgroup analysis showed that UF with larger mean fluid-remove rate (≥200 mL/h) could significantly remove more fluid, lose more weight, and decrease heart failure rehospitalization. Less weight loss for patients with ADHF may correlated to higher percent of ischemic etiology (ischemic etiology ≥50%).

**Conclusion:** Although UF is more effective in removing fluid than diuretics and decrease rehospitalization of heart failure and all causes, there is not enough evidence to prove that UF is superior because of adverse events and mortality in the UF group. The mean fluid-removal rates should be set to ≥200 mL/h. Patient with different etiology may have different effects when treated with UF and it is a weak conclusion.

**Trial registration:** The systematic review was registered with the International Prospective Registry of Systematic Reviews. (https://www.crd.york.ac.uk/prospero/, registration number CRD42021245049).

**Abbreviations:** ADHF = acute decompensated heart failure, CI = confidence interval, MD = mean difference, RCTs = randomized controlled trials, RR = risk ratio, UF = ultrafiltration.

**Keywords:** acute decompensated heart failure, diuretics, meta-analysis, ultrafiltration

1. Introduction

Acute decompensated heart failure (ADHF) is a type of acute heart failure, which refers to patients with a previous history of chronic heart failure. Most of these patients are due to fluid retention, which causes a poor prognosis.[1] Loop diuretics have been recognized as a cornerstone in relieving severe fluid accumulation.[2] However, it remains some shortcomings, such as diuretic resistance and renal dysfunction.[2,3]

Ultrafiltration (UF) is a distinctive way to selectively remove excessive fluid without affecting circulating volume and activating neuro-humoral reaction.[4] The recommendations of ultrafiltration in the ACC/AHA guidelines indicate that UF should be considered for patients with obvious volume overload (Class IIIb, Level of Evidence: B) and intractable congestion not responding to medical therapy (Class IIIb, Level of Evidence: C).[5] The 2016 ESC guidelines do not recommend the routine use of UF.[6]

So far, there is no consistent agreement about whether early UF is the first-line treatment for patients with ADHF. Therefore, the aim of this meta-analysis is to compare UF with diuretics about efficacy and safety for ADHF patients.
2. Methods
Ethical approval was not necessary. As a systematic review, our study is a secondary study of the published literature.

2.1. Search strategy
We searched PubMed, Embase, and Cochrane Library databases using the search terms: “ultrafiltration,” “heart failure,” “cardiac failure,” “randomized controlled trial” for all articles till January 18, 2021. A supplementary search of PubMed was made on May 23, 2021. Reference lists of related studies were screened to identify other articles that did not found online search.

2.2. Study selection
Inclusion criteria: RCTs; the age of patients ≥18 years old and the patients meet the criteria of diagnosis for acute heart failure; the intervention group was ultrafiltration; the comparison group was diuretics; these studies must include one or more designated outcomes. Exclusion criteria: ultrafiltration was performed by continue renal replacement therapy; studies were published over 20 years.

Two reviewers (WMJ and ZYM) independently screened all articles’ titles and abstracts to exclude studies that are unrelated. Second, full-text articles were critically assessed for eligibility, according to inclusion and exclusion criteria. Disagreements were resolved by discussion.

2.3. Assessment of included study and data extraction
Two authors (WMJ and JHX) assessed the quality of the RCTs independently. The risks of bias were assessed by the Cochrane Collaboration’s assessment tool for RCTs.[7] Two authors (WMJ and ZYM) extracted the following data independently. The data of studies included basic information of studies such as country, patients’ age, the male sex, comorbidities, medication, protocols for ultrafiltration and diuretics, and results of studies. The primary outcomes were heart failure rehospitalization, all-cause rehospitalization, mortality. Secondary outcomes were fluid loss and weight loss, adverse events.

2.4. Statistical analysis
RevMan Version 5.4.1 (The Cochrane Collaboration, 2020) was used to analyze the data of included studies. Dichotomous data and continuous data were calculated with Mantel–Haenszel risk ratio (RR) and mean difference (MD), respectively. All outcomes except adverse events were used for meta-analysis. The outcomes of adverse events were list in the table of results of studies. If not providing standard deviation, we used the method of Cochrane handbook to estimate the value. A measure of statistical significance was P=.05, and 95% confidence interval (CI) was used. Heterogeneity with Chi-square Q and I², funnel plots, and Egger P-value were used in this article. Fixed effect model was applied in the process of analysis. If I² >30%, the fixed effect model will be changed to a random model.

3. Results
3.1. Literature search
The study flow diagram was shown in Fig. 1. Six hundred thirty four records were searched online, and 1 record was identified through references. After preliminary screening, 41 full-text articles were assessed by inclusion and exclusion criteria and a total of 12 studies[8–19] were included.

3.2. Study characteristics and data
In the 12 RCTs,[8–19] 1197 patients were involved, 584 in the UF group, 613 in the diuretics group. The patients’ characteristics were listed in Table 1, protocols for UF and diuretics in Table 2, results of studies in Table 3. Six studies were conducted in the USA,[8–12,14] 3 studies in China,[15,18–19] 2 studies in Italy,[13,16] and 1 study in Turkey.[17] The age of patients of included studies ranged from 50.8 to 86.5. The percent of the male sex ranged from 55 to 100. UF was performed by Aquadex system 100 in 4 studies[8–11] and by FQ-16 in 3 studies.[13,18–19] The intervention groups in 3 studies combined UF with diuretics.[8,16,19] One study included patients with diuretic resistance determined by which the patients were given furosemide 160mg/d for 48 hours and 24 hours urine output <0.5 mL/kg/h before randomization.[18]

3.3. Assessment for the risk of bias
The assessment of risks of bias was shown in Fig. 2. The RCTs about UF were open-label trials, so the risk of performance bias was high. Attrition bias existed in 2 studies[9,14] because more patients withdrew in the UF group. Other bias existed in Costanzo et al,[12] because of the early termination of the study.

3.4. Publication bias
The Funnel plot of weight loss was shown in Fig. 3. Despite the heterogeneity of studies, there may be publication bias among the included studies.

3.5. Outcomes of meta-analysis
3.5.1. Heart failure rehospitalization and all-cause rehospitalization. Four studies reported the rehospitalization for heart failure, and 628 patients were involved: 311 for UF, 317 for diuretics. There are 4 studies for all-cause rehospitalization which included 208 patients: 94 for UF, 114 for diuretics. The follow-up period ranged from 1 month to 1 year. The rate of heart failure rehospitalization and all-cause rehospitalization in UF group were significantly lower than that in the diuretics group: RR 0.67 [95% CI: 0.52–0.87; P=.003; I²=53%] (Fig. 4A), RR 0.62 [95% CI: 0.42–0.92; P=.02; I²=14%] (Fig. 4B), respectively. Marenzi et al[16] in heart failure rehospitalization was removed: RR 0.74 [95% CI: 0.56–0.97; P=.03; I²=17%]. The sensitivity analysis for the comparison of all-cause rehospitalization between groups did not change the overall result.

3.5.2. Mortality. Eight studies reported mortality involving 860 patients, 414 in the UF group, and 446 in the diuretics group. Follow-up time ranged from 1 month to 1 year. There was no statistical significance in mortality between UF group and diuretics group: RR 1.09 [95% CI: 0.78–1.51; P=.62; I²=0%] (Fig. 4C). The sensitivity analysis for the comparison of mortality between groups did not change the overall result.

3.5.3. Fluid loss and weight loss. Data on fluid loss was available for 7 studies including 748 patients, 368 in UF, and 377 in the diuretics group. Eleven studies involving 1165 patients provided data on weight loss, 574 patients in UF group, 591
patients in the diuretics group. The data’s recording time ranged from 24 to 96 hours, except for Şeker et al[17] at discharge, Hanna et al[14] Shen et al[18,19] during the intervention period, Hu et al[15] on the 8th day and Marenzi et al[16] at discharge. Fluid loss and weight loss in the UF group were significantly more than that in the diuretics group: MD (fluid loss): 1.47 [95% CI: 0.95–

**Figure 1.** Study flow diagram.

| Study       | Multicenter trial | Country | Patients | Age, y   | Male (%) | LVEF (%) | Ischemic (%) | Hypertension (%) | DM (%) | Cr (pg/ml) | ACEI/ARB (%) | Diuretics (%) | BB (%) |
|-------------|-------------------|---------|----------|----------|----------|----------|--------------|------------------|--------|------------|--------------|--------------|--------|
| Bart 2005   | Yes               | USA     | 40       | 70/70    | 67.5/69.5| 30/35    | 70/51        | 60/65            | 35/53  | 1.9/2.09   | 70/70        | 65/95        | 75/65  |
| Bart 2012   | Yes               | USA     | 188      | 69/66    | 78/72    | 40/34    | 50/50        | 65/67            | 50/50  | 1.9/1.4    | 55/52        | 91/96        | 79/78  |
| Chung 2014  | No                | USA     | 16       | 69/74    | 87.5/100 | 40/34    | 50/50        | 67/67            | 50/50  | 1.9/1.4    | 55/52        | 91/96        | 79/78  |
| Costanzo 2007 | Yes            | USA     | 200      | 62/63    | 70/68    | 40/34    | 50/50        | 69/73            | 50/50  | 1.9/1.4    | 55/52        | 91/96        | 79/78  |
| Costanzo 2016 | Yes            | USA     | 220      | 67/67    | 87/87    | 36.3/36.6| 40/34        | 88.2/83          | 61.6/64| 1.5/1.6    | 38.2/43.2    | 55.4/55.9    | 75/65  |
| Costanzo 2016 | Yes            | Italy   | 221      | 72.4/65.8| 84.2/76  | 34/30    | 40/34        | 82/83           | 40/60  | 1/1.5      | 86.7/80      | 55.4/55.9    | 75/65  |
| Costanzo 2016 | Yes            | USA     | 30       | 60/59    | 84.2/76  | 19/18    | 40/34        | 82/83           | 40/60  | 1.7/1.5    | 100/98.3     | 100/100      | 100/98 |
| Costanzo 2016 | Yes            | China   | 100      | 70.6/73.52| 55/55    | <40%     | 40/34        | 82/83           | 40/60  | 1.7/1.5    | 100/98.3     | 100/100      | 100/98 |
| Costanzo 2016 | No              | Italy   | 36       | 73/75    | 68/66    | 40/34    | 40/34        | 82/83           | 40/60  | 1.7/1.5    | 100/98.3     | 100/100      | 100/98 |
| Costanzo 2016 | No              | Turkey  | 30       | 70/67.5  | 68/66    | 40/34    | 40/34        | 82/83           | 40/60  | 1.7/1.5    | 100/98.3     | 100/100      | 100/98 |
| Costanzo 2016 | No              | China   | 134      | 66.5/66.8| 68/66    | 40/34    | 40/34        | 82/83           | 40/60  | 1.7/1.5    | 100/98.3     | 100/100      | 100/98 |

*A/B = ultrafiltration/diuretics, ACEI = angiotensin-converting enzyme inhibitor, ARB = angiotensin II receptor blocker, BB = beta-blockers, Cr = creatinine, DM = diabetes mellitus, LVEF = left ventricular ejection fraction.*

Table 1

Characteristics of studies.

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Two primary studies have reported that adverse events in the UF group increased compared with the diuretics group: a serious adverse event over the 60 days of follow-up in Bart et al.\(^9\) (UF vs diuretics: 68 vs 54, \(P = .03\)); an adverse event of special interest in Costanzo et al.\(^{12}\) (UF vs diuretics: 34 vs 19, \(P = .018\)). In Bart et al.\(^9\) serious adverse events included cardiovascular disorder, renal failure, bleeding complications, catheter-related complications, etc. In Costanzo et al.\(^{12}\) adverse events of special interest included infection, bleeding, symptomatic hypotension, anemia, acute coronary syndrome, and most of the events need medical intervention. In Şeker et al.\(^{17}\) there were more adverse events in the UF group: (UF vs diuretics: 8 vs 4). The adverse events included hematoma, infection and bleeding complications, hemodialysis, hypotension, cardiac arrest, and death. In Hanna et al.\(^{14}\) adverse events per patient week were greater in the UF group (2.68 for UF vs 2.47 for diuretics, \(P = .41\)).

In Costanzo et al.\(^{11}\) the total number of adverse events in the diuretics group was more than that in the UF group. The adverse events included catheter/needle site, filter, infection, bleeding,
hypotension, worsening heart failure, arrhythmias, cardiac arrest, dialysis, anemia, myocardial infarction, and neurologic. Among these kinds of adverse events, the number of hypotension, arrhythmias, anemia, and dialysis in the UF group were more than that in the diuretics group. In Yancy et al.\[5\] there was 1 death in the UF group during the 30-day follow-up period and one catheter site infection that required treatment. In the UF group of Hu et al.\[15\] two patients had subcutaneous congestion at the puncture site and no patient had an infection or major bleeding. In Shen et al.\[19\] there was 2 died during treatment in the diuretics group, due to worsening heart failure. There was no death in the ultrafiltration group, and no obvious adverse events occurred during and after ultrafiltration. In Chung et al.\[10\] 4 patients in each group developed a transient rise in Cr >0.3 mg/dL above the baseline line.

3.7. Subgroup analysis
3.7.1. Mean fluid-removal rate. According to mean fluid-removal rate, we identified 2 groups: mean fluid-removal rate ≥200 mL/h; mean fluid-removal rate <200 mL/h. Three studies\[10–12\] have reported mean fluid-removal rate. The mean fluid-removal rates in the 6 studies\[8,14–16,18–19\] were identified as ≥200 mL/h by the information provided by these RCTs. The mean fluid-removal rate in 1 RCT\[9\] was identified as <200 mL/h by the information provided by one article.\[22\] Subgroup analyses found a different magnitude of effect in the following aspects: weight loss, fluid loss, and heart failure rehospitalization. The MD of weight loss (≥200 mL/h) was 2.06 [95% CI: 0.92–3.2] compared with 0.14 (95% CI: −0.92–1.20) for lower fluid-removal rate (Fig. 6); the MD of fluid loss (≥200 mL/h) was 2.45 [95% CI: 1.80–3.09] compared with 0.14 (95% CI: −0.19–2.04) for lower fluid-removal rate (Fig. 7); the RR of heart failure rehospitalization (≥200 mL/h) was 0.45 [95% CI: 0.28–0.73] compared with 0.82 (95% CI: 0.60–1.12) for lower fluid-removal rate (Fig. 8).

3.7.2. Ischemic etiology. Seven RCTs\[9–10,12–14,16,19\] have shown the percentage of ischemic etiology for included patients. Ischemic etiology in 3 studies\[9–10,13\] was ≥50%, and the percentage in 4 studies\[12,14,16,19\] was <50%. The MD of weight loss (≥50%) was 0.72 [95% CI: −0.78–2.23] compared with 2.46 (95% CI: 0.71–4.22) for lower percentage of ischemic etiology (Fig. 9).

4. Discussion
Our analysis revealed that UF is a more effective way of removing fluid than diuretics. Rehospitalization for heart failure and all-cause, meanwhile, is lower than diuretics. Our results were partly consistent with Wobbe meta-analysis.\[20\] Moreover, we updated the review by adding 4 more studies, and heterogeneity was lower in our analysis. Heterogeneity still existed in weight loss regardless of sensitivity analysis, but not in fluid loss. The
probable reasons were variations in the protocols of both groups such as differences in water and sodium intake.

It is not surprising that ultrafiltration’s ability in removing fluid is better than diuretics. There are 2 reasons that we supposed. Firstly, we can adjust the speed fluid loss and duration of UF according to patients’ situations. However, when using diuretics, it’s not so easy to control it, because every patient responds differently to diuretics. Secondly, we must pay attention to the fact that the majority of people in most of the included studies have been exposed to diuretics, which may decrease the efficiency of diuretics. Diuretic resistance may exist among some patients, this term, however, does not have a well-accepted definition so far.[2]

The readmission rate for heart failure, as we considered, was lower than diuretics due to the improvement of diuretic resistance. The dose of diuretics could be decreased after performing UF,[9] and sensitivity to diuretics can be restored in the process. Another reason may be related to removing more extra fluid. On the other hand, UF do not activate neuro-humoral activity, which was proved by Giglioli et al.[13] All-cause rehospitalization was significantly lower than the diuretic group.

Figure 4. A, Heart failure rehospitalization. B, All-cause rehospitalization. C, Mortality.

Indeed, heart failure readmission was involved. The result implies that UF, directly or indirectly, exerts a good effect on some of the disease that related heart failure.

A meta-analysis of Wobbe et al[20] suggested that UF is a safe and effective treatment without a difference in renal impairment, and lower incidences of worsening heart failure. Shi et al[21] concluded that UF did not have a difference in worsening heart failure, cardiovascular outcome, hemorrhage, the change of serum creatinine and infection, but not in hypotension. However, we cannot deny the fact that central venous catheter and heparin are used during the process of UF, and it must increase the risks of infection and hemorrhage. On the other hand, UF has, as we proved, the ability to removing more fluid, which may have the chance of causing renal dysfunction, although the meta-analysis of BW and XS did not reveal renal impairment. In our experience, patients with vascular and structural diseases of the kidney are more prone to renal impairment.

Subgroup analysis showed that UF with larger mean fluid-remove rate (≥200mL/h) could significantly remove more fluid and lose more weight, most importantly, decrease heart failure
rehospitalization when compared with lower mean fluid-remove rate (<200mL/h). Consequently, fluid-remove rate of UF is important for patients with ADHF. Larger fluid-remove rate may result in more fluid remove. Enough reduction of fluid excess will have a good effect on relieving decongestion and other good outcomes. In addition, suitable fluid-remove rate could reduce the risk of filter clogging. Subgroup analysis also implied that less weight loss for patients with ADHF in the process of UF correlated to higher percent of ischemic etiology (ischemic etiology ≥50%) and it is a weak conclusion.

More high-quality RCTs should be designed and implemented to enhance the level of evidence of the benefit of UF in the future.

Figure 5. A, Fluid loss. B, Weight loss.

Figure 6. Subgroup analysis of weight loss for mean fluid-remove rate.
As a treatment of ADHF, UF must be more suitable for some kinds of patients. Our study showed that patients with ischemic etiology may suffer from less weight loss. Therefore, future studies should figure out what kinds of patients are suitable for UF. How to use UF more safely and effectively should be focused on in future studies. Firstly, the fluid-removal rate is important. It is not suitable that the rate is too fast or slow. Besides, the fluid-removal rate could be adjusted by patients’ conditions. Secondly, UF therapy should be precisely monitored to avoid hypoperfusion. Avoiding other adverse events such as bleeding and infection is also crucial. Lastly, more patients should be included in future studies to explore adverse events. Meanwhile, total adverse events are not an ideal end point, because diuretics and UF have different characteristics with respect to adverse events. For example, bleeding and infection are more likely to occur during ultrafiltration.

5. Conclusion

UF is more effective in removing fluid than diuretics and can decrease rehospitalization of heart failure and all causes. UF have a better function in solving “water problems” and improving diuretic resistance. However, there were inconsistent agreements about which group have more total adverse events and UF do not improve mortality in patients with ADHF. Therefore, we can’t draw a conclusion that UF is superior than diuretics. UF with larger mean fluid-removal rate (≥200mL/h) could significantly remove more fluid, lose more weight, and decrease heart failure
rehospitalization. We can hold a clue that less weight loss for patients with ADHF may associated to higher percent of ischemic etiology. However, our study still had limitations. There was a high heterogeneity about weight loss and most RCTs did not provide enough information to assess the bias of RCTs. Due to the heterogeneity of the kinds of adverse events in all studies, we cannot make a consistent conclusion about the safety of UF.

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Author contributions
Conceptualization: Mengjun Wang.
Data curation: Mengjun Wang, Yanmei Zheng.
Formal analysis: Mengjun Wang.
Methodology: Mengjun Wang, Hongxu Jin.
Software: Mengjun Wang.
Supervision: Hongxu Jin.
Writing – original draft: Mengjun Wang.
Writing – review & editing: Yanmei Zheng, Hongxu Jin.

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