ALL TAP, NO GAIN: LESSONS LEARNED FROM THE TAP-IT TRIAL

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The clinical question

Does upfront therapeutic thoracentesis improve outcomes in patients with acute heart failure with reduced left ventricular EF and a non-negligible pleural effusion compared to standard therapy alone?

Take Home Message

Routine therapeutic thoracentesis performed upfront in patients hospitalized with acute heart failure and pleural effusion does not improve clinical outcomes including days alive out of the hospital, rehospitalization, length of stay, or quality of life. While shown to be safe, thoracentesis should be reserved for carefully selected patients who remain symptomatic or have refractory effusions. Guideline-directed medical therapy and diuresis should remain the cornerstone of acute heart failure management.

Background

Pleural effusion is a common complication of acute heart failure, occurring in more than half of hospital admissions. Approximately 20% of patients present with a large effusion occupying more than one-third of the hemithorax. Thoracentesis can provide rapid symptomatic relief, but it carries procedural risks such as pneumothorax, bleeding, and infection...

... Despite its frequent use in clinical practice, no randomized controlled trials have previously evaluated its role for management of pleural effusions caused by acute decompensated heart failure. As a result, current treatment guidelines provide no recommendations regarding the routine use or timing of thoracentesis in this setting.
In recent years, the use of thoracentesis in heart failure patients has been rising, underscoring the urgent need for high-quality evidence to guide practice. The TAP-IT trial was designed to address this gap, evaluating whether routine thoracentesis in addition to standard care improves short-term outcomes in patients with acute heart failure and reduced ejection fraction.

Study design

Study design: Multi-center, pragmatic, open label, parallel two-group, superiority randomized controlled trial

Primary outcome: The number of days alive out of the hospital (DAOH) in the 90 days after randomization.

Secondary Outcome(s):

Clinical outcomes
- Index admission length
- All-cause mortality (90 days)
- Time to first all-cause hospitalization or all-cause death
- Days alive and not hospitalized for heart failure
- Heart failure–related hospitalization

Patient-reported outcomes
- Quality of life: Kansas City Cardiomyopathy Questionnaire (KCCQ) at days 14 and 90
- Patient satisfaction with treatment and care during index admission

Safety outcomes
- Number of severe and common thoracentesis-related complications
- Thromboembolic events within 30 days

Intervention (s)

Participants randomized to the thoracentesis group underwent therapeutic thoracentesis in addition to guideline-directed medical therapy including intravenous loop diuretics according to clinical judgment. Thoracentesis was performed using ultrasound guidance and most commonly by insertion of a pigtail catheter for fluid drainage. The timing of the procedure was during the index hospitalization after randomization, and drainage was continued until determined by the treating physician to be complete or clinically adequate. The median drainage volume was about 1062 mL. The control group received GDMT alone, with thoracentesis permitted only if the patient clinically deteriorated or if the pleural effusion remained unresolved despite 5 days of therapy.

Population

Inclusion criteria:

- Adults ≥18 years admitted with acute heart failure (new-onset or decompensated chronic CHF)
- LVEF ≤45%
- Presence of a clinically relevant pleural effusion deemed amenable for thoracentesis by the treating physician
- Effusion considered to be of cardiac origin
- Suitability for thoracentesis determined by imaging available in the clinical setting

Exclusion criteria

- Indication for diagnostic thoracentesis
- Contraindication to thoracentesis
- Severe hemodynamic instability or respiratory failure
- Massive pleural effusion (> ⅔ of the hemithorax)
- Pulmonary or pleural infection
- Intrathoracic procedure within 3 months (including thoracentesis)
- Severe aortic stenosis
- eGFR <15 mL/min/1.73 m^2 or on dialysis
- Planned or expected hospital stay >10 days for reasons other than heart failure

Baseline characteristics

135 patients with a median age of 81 years were enrolled (IQR 75–84). One-third of participants were women. The median left ventricular ejection fraction was 25% (IQR 20–35%), and 73% of the subjects presented with bilateral pleural effusions.
Most patients had advanced symptoms at baseline, with 95% classified as NYHA class III or IV. 53% had new-onset heart failure. The majority had an ischemic etiology of heart failure. 10% of the patients had cardiac resynchronization therapy and 15% had an implantable cardioverter-defibrillator.
Hypertension and atrial fibrillation/flutter were among the most common cardiovascular comorbidities. Lifestyle risk factors included active or former smoking in more than half the cohort, and 20% reported alcohol consumption above recommended thresholds.
Laboratory values at admission reflected significant systemic illness. The median NT-proBNP was about 5900 pg/mL, creatinine around 100–110 µmol/L and estimated GFR about 56–62 mL/min/1.73 m^2. Hemoglobin levels averaged around 8 mmol/L, sodium was generally preserved at 139 mmol/L, and C-reactive protein was mildly elevated.
At baseline, approximately 53% were on an ACE inhibitor, ARB, or ARNI, 42% on a beta-blocker, 19% on a mineralocorticoid receptor antagonist, and 16% on an SGLT2 inhibitor. Nearly half of the patients (49%) were receiving anticoagulation.

Outcomes

Primary outcome:

- Days Alive Out of Hospital (DAOH) at 90 days
  - Thoracentesis group: 84 days (IQR 77–86)
  - Control group: 82 days (IQR 73–86)
  - Mann-Whitney parameter 0.54 (95% CI 0.44–0.63); p=0.42
  - No significant difference noted, and results were consistent across sensitivity analyses and subgroups

Secondary outcomes

- Clinical outcomes
  - Index admission length: Median 5 days in both groups (p=0.69)
  - 90-day all-cause mortality: 13% in both groups (9/68 thoracentesis vs. 9/67 control; p=0.90)
  - In-hospital mortality: 3% in each group (2 patients each)
  - All-cause rehospitalization (90 days): Thoracentesis 41% vs. Control 42% (p=0.99)
  - Composite outcome (death or first rehospitalization): No difference (p>0.99)
  - Days alive and not hospitalized for heart failure (90 days): Thoracentesis 85 (IQR 84–87) vs. Control 84 (IQR 80–86); p=0.16
  - Subgroup analyses (anticoagulation status, CHF type, effusion size): No differences
  - Loop diuretic therapy: Intensified by median 80 mg/day in both groups, with no difference between groups at discharge (p=0.92)
  - Weight loss: Control –4.5 kg vs. Thoracentesis –5.0 kg; p=0.41
  - Renal function at discharge: Creatinine similar (Control 111 µmol/L vs. Thoracentesis 106 µmol/L; p=0.45)
  - GDMT at discharge: Marked increase in use across both groups (ACEI/ARB/ARNI 71%, beta-blockers 64%, MRAs 43%, SGLT2i 38%)

- **Patient-Reported Outcomes**
  - KCCQ response rates: 72% at day 14, 64% at day 90 (no group difference)
  - KCCQ overall summary score: No difference at day 14 or 90
  - Exploratory analysis: No significant differences
  - Patient satisfaction: Median score 4/5 in both groups

- **Adverse events**
  - Serious complications during index admission: 7% overall, similar between groups
  - Thoracenteses performed: 80
  - Pneumothorax: 4/80 (5%); 1 required chest drain (1% major complication rate)
  - Other major complications: None (no major bleeding, organ laceration, empyema, or re-expansion pulmonary edema)
  - Minor complications: 20/80 (25%), included pain, leakage, accidental removal, minor bleeding
  - Overall complication rate: 26%

Commentary

Study strengths:

The TAP-IT trial is the first multicenter, randomized, pragmatic trial to evaluate the effects of therapeutic thoracentesis in patients with acute heart failure and pleural effusion. By randomization and enrollment across 10 hospitals in Denmark, including tertiary centers, the study minimized bias and provided robust, real-world evidence.
The trial assessed a broad range of outcomes including post-hospitalization survival, rehospitalization, patient-reported quality of life, satisfaction, renal function, and safety, offering a well-rounded evaluation of the intervention.
The study confirmed that thoracentesis is a safe procedure, with only one major complication (1%) among 80 procedures performed and no cases of major bleeding, infection, or re-expansion pulmonary edema. The trial also demonstrated consistency across multiple sensitivity and subgroup analyses, including anticoagulation status, type of heart failure (new onset vs. decompensated chronic), and effusion size, strengthening confidence in the findings.
Most critically, the study showed that routine thoracentesis did not improve outcomes. The primary outcome of days alive out of hospital was nearly identical between groups (84 vs. 82 days, p=0.42), and there were no differences in mortality (13% vs. 13%), rehospitalization (41% vs. 42%), or quality of life. These results provide strong evidence to guide clinical practice and challenge assumptions about the routine benefit of thoracentesis in this setting.

Study Limitations:

The TAP-IT trial has several limitations that require consideration. As an open-label interventional trial, there is an inherent risk of bias. Although the chosen primary outcome of days alive out of hospital (DAOH) at 90 days is clinically relevant and relatively objective, the lack of blinding may have influenced physicians' decisions regarding discharge or readmission. Similarly, patient-reported outcomes such as quality of life and satisfaction are prone to survivor bias and attrition bias, as patients with poorer health were less likely to return questionnaires. This frail population, with a heavy burden of cardiovascular and non-cardiovascular comorbidities, was particularly susceptible to such effects.
The study also faced issues of statistical power. Greater variability in DAOH than anticipated reduced the ability to detect smaller or moderate differences between groups, lowering the power from the expected 90%. In addition, the trial did not employ a protocolized assessment of decongestion, and no routine imaging was used to confirm the completeness of fluid drainage, limiting interpretation of the procedural effect. While the median drainage volume (about 1L) was consistent with prior observational studies showing symptom relief in outpatients, the lack of standardized decongestion metrics leaves uncertainty about the physiological impact.
The timing of thoracentesis was also influenced by clinical logistics. The procedure occurred a median of 22 hours after randomization, often delayed by the need to pause anticoagulation therapy in nearly half the participants. This reflects real-world practice but may have reduced any potential impact on early outcomes, such as length of stay.
Finally, the study's modest sample size and advanced age of participants (median 81 years) limit generalizability. The findings may not apply to younger patients with fewer comorbidities, and subgroup analyses (including sex differences and effusion size categories) should be interpreted with caution.

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Suggested Reading

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