Research Roundup

Herrmann JJ, Brunner-La Rocca HP, Baltussen LE, et al. Liberal Fluid Intake Versus Fluid Restriction in Chronic Heart Failure: A Randomized Clinical Trial. Nat Med 2025;Mar 30:[Epub ahead of print].

Fluid restriction for people diagnosed with chronic heart failure (HF) has been a mainstay of care, but there is limited evidence to support this approach. The FRESH-UP trial, conducted across 7 sites in the Netherlands, provides health professionals with new evidence upon which to base their recommendations for oral fluid intake.

A sample of 504 participants, diagnosed with HF, were randomly allocated (1:1) to either a fluid restriction of 1500 mLs per day (n=250) or standardized lifestyle advice of liberal fluid intake with no restriction (n=250) in an outpatient setting for a 3-month period. Participants were predominantly male (67.3%), with a mean age of 69.2 years, had been treated for HF for over 6 months (NYHA class II or III).

The primary outcome was the Kansas City Cardiomyopathy Questionnaire-Overall Summary Score (KCCQ-OSS). The score was 74.0 in the liberal fluid intake group compared to 72.2 in the fluid restricted group at 3 months. There was no statistically significant difference in KCCQ-OSS after adjusting for baseline scores.

Perceived thirst distress was measured as a secondary outcome using the Thirst Distress Scale for patients with HF [TDS-HF]. Patients in the liberal fluid arm reported lower perceived thirst distress than the liberal fluid group after adjustment of baseline scores.

The authors concluded that findings demonstrated that for patients with chronic heart failure (HF), liberal fluid intake did not result in a significant difference in health status vs. fluid restriction up to 1500 mL per day and lowered perceived thirst distress.

Clinical Implications

The findings suggest that liberal fluid intake may be safe in people with chronic HF and may improve their quality of life. This challenges the widespread recommendations regarding fluid

restriction as an intervention for all people with HF supporting a more person-centred approach. However, caution in the interpretation of results is required given that few of the liberal fluid group drank greater than 2 Litres a day. Additional research is needed to replicate this finding and whether the results are consistent in people with more advanced HF.

PRESTIGE-AF: Stroke Prevention in Intracerebral Haemorrhage Survivors with Atrial Fibrillation

Citation: Veltkamp, R., Korompoki, E., Harvey, K.H., et al. (2025). Direct oral anticoagulants versus no anticoagulation for the prevention of stroke in survivors of intracerebral haemorrhage with atrial fibrillation (PRESTIGE-AF): a multicentre, open-label, randomised, phase 3 trial. The Lancet, 405(10313), 927–936.

Atrial fibrillation (AF) significantly increases the risk of ischaemic stroke and is typically managed with anticoagulation therapy to prevent thromboembolic events. However, in patients with a history of intracerebral haemorrhage (ICH), resuming anticoagulation poses a complex clinical dilemma due to the high risk of recurrent bleeding, and current guidelines offer limited direction as these individuals are often excluded from major trials. The PRESTIGE-AF trial aims to address this critical knowledge gap by evaluating stroke prevention strategies specifically in AF patients with prior ICH, where treatment decisions require careful balancing of thromboembolic risk against the potential for further haemorrhagic events.

This landmark trial involved 319 participants from 75 hospitals across six European countries. Patients were randomised to receive either a direct oral anticoagulant (DOAC) or no anticoagulation therapy. The trial utilised a hierarchical composite endpoint incorporating both efficacy (reduction in ischaemic stroke) and safety (avoidance of recurrent ICH), with a median follow-up of 1.4 years.

DOAC treatment was associated with a significant reduction in ischaemic stroke (hazard ratio [HR] 0.05; 95% confidence interval [CI] 0.01–0.36), corresponding to an absolute risk reduction of 7.77 events per 100 patient-years (number needed to treat = 13). However, DOACs also carried a substantially increased risk of recurrent ICH (HR 10.89; 90% CI 1.95–

60.72), which exceeded the non-inferiority margin and raised safety concerns in certain patient subgroups.

While all-cause mortality was slightly lower in the DOAC group (10% vs. 13%), serious adverse events occurred in 44% of the DOAC group compared to 55% of the control group. DOAC therapy was also linked to fewer composite cardiovascular events, but a higher incidence of major bleeding overall.

Clinical Implications

The findings support a personalised approach to anticoagulation decision-making following ICH. DOACs may be suitable in selected patients with high thromboembolic risk, non-lobar ICH, and controlled blood pressure. Shared decision-making, incorporating patient preferences and clinical risk profiles, is essential. This trial provides the first high-quality evidence to inform treatment in this high-risk population.

Understanding Patient Perspectives on Stroke Prevention Post-ICH: A Qualitative Study from PRESTIGE-AF

Citation: Ivany, E., Lotto, R.R., Lip, G.Y.H., Lane, D.A. (2025). Patients' views on stroke prevention for atrial fibrillation after an intracerebral haemorrhage: a qualitative study. European Journal of Cardiovascular Nursing, 24(3), 413–419.

In parallel with the clinical trial, the PRESTIGE-AF programme incorporated a qualitative study to understand how patients perceive stroke prevention in the context of AF following ICH. Semi-structured interviews were conducted with 12 participants from UK stroke centres. Thematic analysis identified complex interplays between clinical advice, personal values, and levels of understanding.

Patients commonly framed treatment decisions in relation to preserving their everyday functioning and overall quality of life. Oral anticoagulants were often perceived as routine medications, with little recognition of the potential risks or complexities associated with their use. Most participants adopted a passive role in the decision-making process, frequently

deferring to the expertise of clinicians and entrusting them with the responsibility for treatment choices.

However, gaps in communication were apparent. Many participants demonstrated limited understanding of their diagnosis, associated stroke risk, or the rationale behind treatment recommendations. While trust in healthcare professionals was generally high, this often appeared to substitute for informed engagement, with decisions accepted rather than actively understood. Family members, particularly close relatives, played a key role in supporting patients to interpret clinical information and navigate the decision-making process.

Clinical Implications

Effective stroke prevention communication necessitates strategies that are both clear and accessible, especially for patients facing cognitive or emotional difficulties. Implementing person-centred care approaches can significantly enhance health literacy and encourage shared decision-making. Healthcare professionals, including nurses and allied health staff, play a crucial role in demystifying complex medical information, thereby enabling patients and their families to make informed and confident treatment choices.

Representation of Women in Atrial Fibrillation Ablation Trials: A Systematic Review

Citation: Marinigh, R., Lowres, N., Lau, D.H., et al. (2024). Representation of Women in Atrial Fibrillation Ablation Randomized Controlled Trials: Systematic Review. Journal of the American Heart Association, 13:e035181.

This systematic review examined 80 randomised controlled trials (RCTs) of catheter ablation for AF to evaluate the extent and quality of female representation. Despite well-established sex differences in AF symptomatology, risk, and outcomes, female participants remain significantly underrepresented in clinical trials evaluating catheter ablation as a treatment for AF.

The median proportion of female participants across trials was only 26%, with some enrolling as few as 11%. Sex-specific outcome reporting was uncommon—only 16% of studies included such analyses—and no trial was powered to detect differences between sexes. Women who were included tended to be older and present with more comorbidities than their male counterparts, suggesting a selection bias that may impact generalisability.

Clinical Implications

The underrepresentation of women in AF trials limits the generalisability of findings and contributes to ongoing disparities in cardiovascular care. Trial design must evolve to include sex-specific recruitment targets, outcome analyses, and justification for imbalances. Clinicians must remain vigilant when interpreting data, ensuring that care strategies are not only evidence-based but also gender-sensitive and inclusive of the diverse needs of patients.