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This is a Fresenius Medical Care summary of:

The CONVINCE randomized trial found positive effects on quality of life for patients with chronic kidney disease treated with hemodiafiltration

Rose M, et al. Kidney Int 2024 Jul 30: S0085-2538(24)00534-9. doi: 10.1016/j.kint.2024.07.014. Epub ahead of print. PMID: 39089577.

Study Design and Methods

The CONVINCE trial demonstrated a survival benefit for patients receiving high-volume hemodiafiltration (HVHDF) compared with high-flux hemodialysis (HD).

A secondary objective in this randomized controlled trial (RCT) was to evaluate the impact on health-related quality of life (HRQoL).

– A patient-reported outcome (PRO) is any health report provided directly by the patient.

– HRQoL is one of the most important patient-reported outcomes.

– The patient's perceptions of how renal replacement therapies impact physical and psychological well-being are important.

To assess HRQoL, electronic patient-reported outcome measures from the Patient-Reported Outcome Measurement Information System (PROMIS) were used.

– These comprise the three fundamental health domains as defined by the World Health Organization:

  · **Physical Health** (physical function, fatigue, pain interference, sleep disturbance),

  · **Mental Health** (depression, anxiety, cognitive function), and

  · **Social Health** (social participation).

– PROs from 1,291 patients were collected at baseline and every 3 months until completion of the study or treatment.

The mean change from baseline after 30 months between HVHDF and HD were assessed for all HRQoL domains.

A linear-mixed model was used to assess HRQoL change from baseline through follow-up time points.

To account for the mortality difference demonstrated in CONVINCE, a post-hoc joint model was conducted to investigate the robustness of the linear-mixed model. The joint model considers the potential dependency of self-reported health status measures and observed differences on mortality rates, thereby reducing the potential bias in the linear-mixed model.

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Results

Throughout the study, there was a small-to-modest deterioration in all HRQoL domains for both groups, with a slower worsening for all HRQoL domains in the HVHDF group.

After 30 months, the overall HRQoL (including all domains) was significantly better for the HVHDF group than the HD group (p = 0.006).

Cognitive function in the HVHDF group declined at half the rate of the HD group (linear-mixed and joint model).

Based on the joint model, the HVHDF group reported significantly slower deterioration in physical function, cognitive function, pain interference, and the ability to participate in social activities compared to the HD group.

Strengths & Limitations

The CONVINCE trial provided a comprehensive and robust evaluation of HRQoL by conducting more frequent and detailed assessments of patient-reported health data than any previous RCTs.

It is the largest nephrology trial that involved patients in developing the questionnaire and using novel electronic PRO measures.

There is no established threshold for PROMIS measures that has been determined to be clinically meaningful to patients with kidney replacement therapy.

The investigated population had an overall lower risk of death than reported in other studies, potentially limiting generalizability of the results.

Conclusions

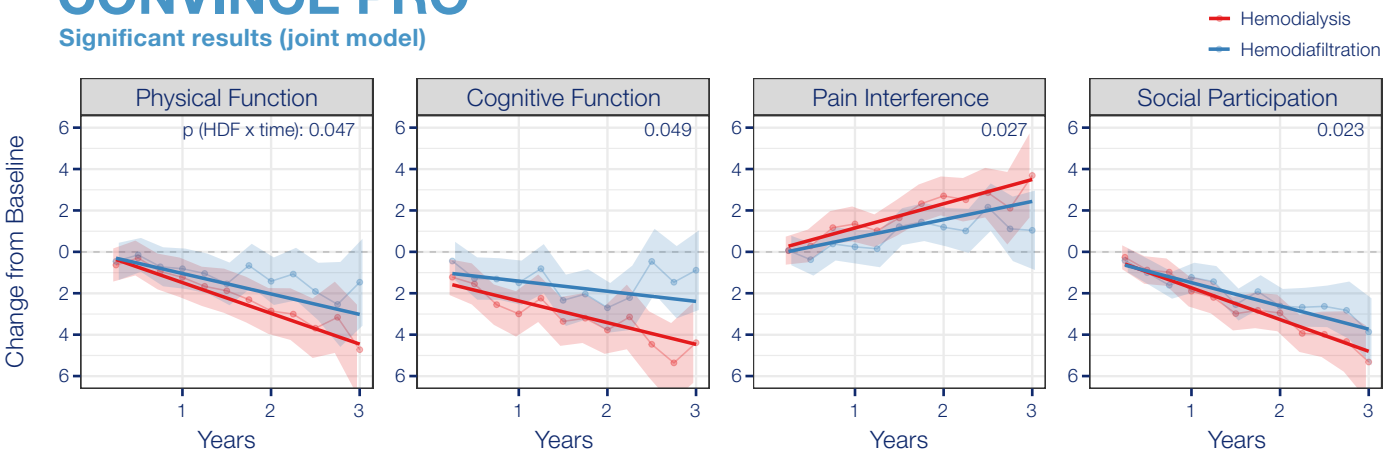
CONVINCE participants reported a slow but constant decline in all HRQoL parameters.

For all domains, HVHDF sustained HRQoL more effectively than HD; this was most pronounced for cognitive function.

Similar to the observed survival benefits in CONVINCE, consistent delivery of HVHDF provides continued beneficial effects on HRQoL over time.

CONVINCE PRO

Significant results (joint model)



Note. Unpublished figure as provided by the CONVINCE consortium, based on joint model described in Rose et al., Kidney International 2024. PRO = patient-reported outcomes. Figure on file.

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