

## Abstract

### ISOQOL, 27<sup>th</sup> Annual Conference in Prague

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*Title:* Assessment of generic and dialysis-related fatigue – identification of individual trajectories and investigation of ecological validity

*Aims:* Fatigue is considered one of the most important patient-reported outcomes (PROs) in the field of end-stage kidney disease (ESKD). However, it is not only related to the disease itself, but also a consequence of the continuous renal replacement therapy. Thus, different aspects of fatigue in ESKD patients undergoing dialysis need to be addressed, such as generic fatigue as well as dialysis-related fatigue. This study investigates the assessment of fatigue in patients with ESKD including trajectory patterns related to hemodialysis sessions, and explores ecological validity of the fatigue instrument from the Patient-Reported Outcomes Measurement Information System (PROMIS).

*Methods:* PRO data of the CONVINCE trial (Trial NL 6942) is used. While recruitment is ongoing, currently  $n=423$  hemodialysis patients have completed the screening assessment of the trial, using an electronic data capturing tool. Generic fatigue is measured by a six-item customized short form of PROMIS<sup>®</sup>. Trajectories of dialysis-related fatigue (i.e., before, during, and three different time points after dialysis) are captured using a retrospective time point-related measurement approach. Dialysis-related fatigue was analyzed as quasi longitudinal data. Ecological validity was evaluated by correlating the PROMIS<sup>®</sup> fatigue score with the dialysis-related measure. Growth curve mixture models were fitted to explore latent fatigue trajectory patterns (i.e. latent classes of individual fatigue trajectories) among the hemodialysis patients.

*Results:* Mean PROMIS<sup>®</sup> fatigue T-score of hemodialysis patients was 49.66 ( $SD= 9.24$ ). Generic fatigue scores and dialysis-related fatigue items correlated moderately between  $r=.49$  and  $r=.61$ .

A fatigue trajectory curve including two independent fatigue peaks (during dialysis and the evening after dialysis) followed by a recovery phase with decreasing fatigue levels approximated the data well. Three distinct classes with different fatigue trajectories (low fatigue, high fatigue, peak fatigue) were identified.

*Conclusion:* The retrospective PROMIS fatigue short-form does only partly reflect fatigue levels before, during and after dialysis. The identification of subgroups of fatigue trajectories during dialysis could help to improve individual treatment in hemodialysis patients.

Word count: 311 words (350 words max)