Comparison of on-line HDF modes: automated TMP control vs. volume control on achieved convective volume and middle molecule clearance


1 Italian Cooperative Study on High Volume On-Line HDF, Italy

Introduction-Aim:

Mixed diffusive-convective dialysis therapies like hemodiafiltration offer greater removal capabilities than conventional dialysis, especially for mid to high molecular weight uremic toxins. In HDF the extent of removal of β2m and other large uremic solutes depends on the delivered total ultrafiltration volume (convective volume)[1].

Analysis of available study (CONTRAST, Turkish HDF trial) indicate that HDF patients who were given a substitution volume above 17.5 L/treatment had a significantly reduced risk of overall mortality (by 46%) and cardiovascular mortality (by 71%) compared to HD.

In standard on-line HDF, the total ultrafiltration (UF) rate is kept constant throughout the session; in automated pressure-control mode, ULTRACONTROL™, the dialysis monitor automatically scans a range of TMPs to find the best UF-TMP operating point [2,3]. The aim of this study was to compare these different ways of performing on-line postdilution HDF treatment in regards to achieved convective volume (CV) and middle molecule dialysis efficiency: through standard volume control (sOL-HDF) and through automated control of transmembrane pressure (UC-HDF).

Methods:

The ULTRACONTROL™ is a biofeedback system that controlling in a double loop the transmembrane pressure (TMP) and its set point. This system scans the TMP (range 100–350 mm Hg) by incremental steps, to achieve the highest UF rate and filtration fraction (FF). The maximum TMP set point is reached when the total UF volume does not increase any more (fig. 1)[3].

We enrolled 30 ESRD patients (55.9±14.0 years, 20/10 M/F) in this randomized prospective cross-over study. The patients were randomized to receive a 3-months period of sOL-HDF treatments (fixed exchanged volume) followed by UC-HDF for further 3 months or vice versa (fig. 2). All treatments were delivered using AK200 ULTRA S dialysis machine and a 2.1 m² Polyfhyll H dialyzer. In sOL-HDF, the convective volume was set according to a FF greater than or equal to 25% [4]; in UC-HDF therapy it was driven by a ULTRACONTROL™ system. Patients maintained their treatment time, blood flow rate and anticoagulant regimen unchanged throughout the study. Primary response variables were: exchanged volume, average β2-microglobulin (β2m) [5] and phosphate (P) [6] clearances. Secondary response variables were: β2m pre and post-dialysis (estimated by a kinetic model [7,8]) and nurse workload (calculated as number of call-free sessions and type of interventions).

Statistics: The descriptive analysis was based as the mean ± standard error of the mean for the continuously distributed variables and frequency/percentage for discrete variables. Inferential statistics included two tailed t-test for paired data, ANOVA and χ² test, considering, as a significant, a probability value of less than 0.05. The SPSS 15.0 statistical package was used for the analysis.

Results:

The UC-HDF mode achieved a greater substitution (fig. 3a), CV (23.8±3.9 vs. 19.8±4.8 L; p<0.001) and FF (32.3±0.8 vs. 26.9±1.9 %, p<0.001) than sOL-HDF. In UC-HDF mode the biofeedback system set and controlled the TMP value, while in sOL-HDF the TMP was uncontrolled and varied during treatment according to current rheological conditions and infusion settings. The average TMP values were higher in UC-HDF than sOL-HDF (fig.3, right panel, from 124±34 to 216±48 mmHg vs. from 80±49 to 210±42 mmHg).

The estimated β2m concentrations at the beginning of dialysis were similar in the two modalities, while they differed significantly at the end of the treatment. The average clearance values of β2m (fig.4, left panel) and P (fig.4, right panel) were higher in UC-HDF than sOL-HDF (respectively 123±24 vs. 111±22 ml/min, p=0.01 and 158±26 vs. 152±25 ml/min, p=0.05).

Moreover, the UC-HDF mode led to a significantly increased rate of call-free sessions from 88% to 97% (p<0.001), reduced number of nurse interventions related to infusion adjustment (from 7.9% to 0.8%, p<0001) and fewer hypotension events (from 2.3% to 1.1%, p<0.05).

Conclusions:

This study showed that the biofeedback module, applied to the automatic control of transmembrane pressure in postdilution on-line HDF (ULTRACONTROL™), results in higher convective volumes and correspondingly higher β2m and P clearances.

By making the HDF treatment more automated and less complex to perform, it significantly reduced the HDF-related workload for the staff. We believe these are clinically important benefits, whenever there is in chronic dialysis patients an indication to perform on-line hemodiafiltration instead of high-flux hemodialysis.

References: