Sa.La.To Study: Permeability characterization of new dialytic membrane

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BACKGROUND

It is estimated that more than 1.2 million people worldwide suffer from end-stage renal disease (ESRD) frequently associated with the uremic syndrome that leads to an increase in the morbidity and mortality rate. Although the pathophysiological process is not completely understood, the retention of a high number of toxic compounds (o solutes) normally eliminated by healthy kidneys, seems to play an important role. Uremic toxins represent an heterogeneous group of substances which includes organic compounds and peptides both in their "native" form and modified by post-translational modifications.

It is known that middle and high MW solutes play a key role in the uremic syndrome. However, standard HDF membranes are unable to depurate solutes with MW greater than 18 kDa;. The aim of the study was to evaluate the performance of a new, more permeable dialytic membrane (Synclear 02) in term of middle MW toxin removal.

METHODS

Ten ESRD patients were selected within SaLaTo study (that recruited 40 patients in 18 Sardinian dialysis centre), for a prospective, multicenter, randomized, crossover study in order to compare the extraction capability of two membranes used in HFR therapy: Synclear 02 (Supra treatment) and Polyphenylene High Flux (pHF) (standard HFR treatment).
After a 4-month washout stabilization period in on-line HDF, each patient was randomized to a sequence of treatments (HFR followed by SUPRA or viceversa) with each treatment applied over 6 months.
Plasma and pre-cartridge ultrafiltrate (UF) samples were used to determine Retinol Binding Protein (RBP), β-2 microglobulin (β2M), α-1 acid glycoprotein (A1AG1), Tumor Necrosis Factor-α (TNF-α), Complement Factor D (CFD) and Leptin levels after 30 minutes from the start of dialytic sessions (Fig1).
RBP, β2M, and A1AG1 were determined by nephelometric assays (BNII, Siemens Healthcare Diagnostics, Tarrytown, NY, USA); TNF-α, CFD and Leptin were evaluated by Solid Phase Sandwich ELISA (Quantikine ELISA kit, R&D System, Minneapolis, MN, USA).

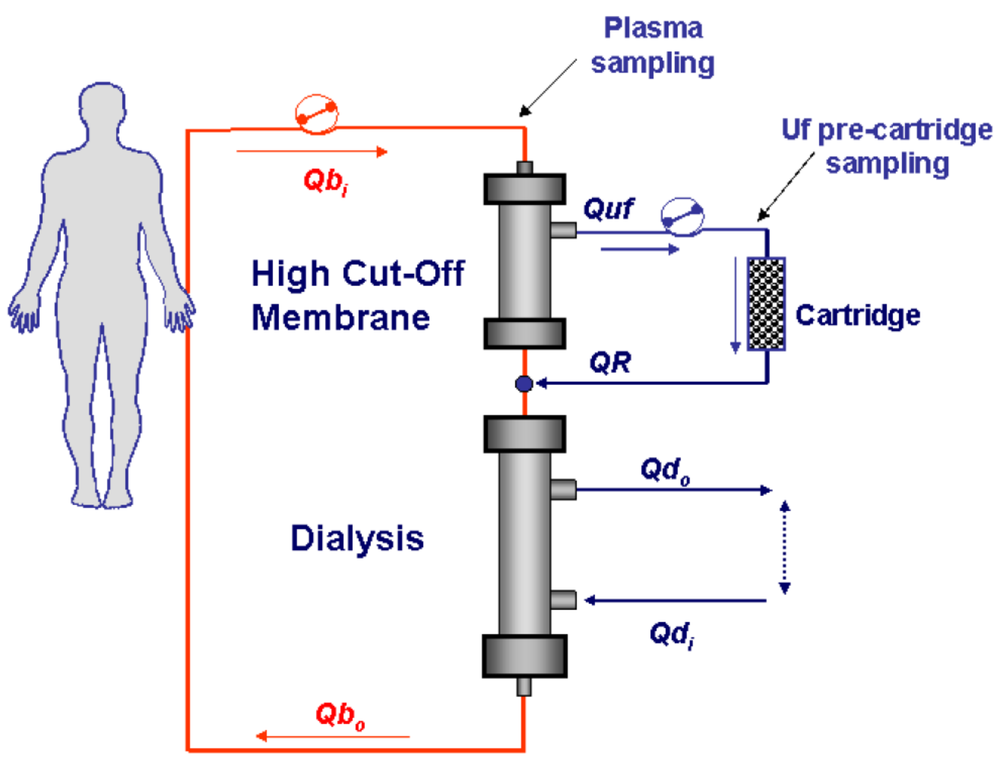

Fig1. Schematic representation of HFR architecture; the arrows indicate sampling point along circuit.

RESULTS

Plasma and UF levels were evaluated both at the start and at the end of first treatment period as well as at the end of the second, post-crossover period. In the long term, no statistically significant variations of pre dialysis levels were found (data not shown).
The extraction capability was evaluated as percentage ratio between UF and plasma concentrations; Statistically significant differences between HFR and SUPRA extraction capabilities were found for RBP (4% vs13%, respectively, p=0,0003), β2M (67% vs 80%, p=0,011), A1AG1 (0% vs 8% p<0,0001) and Leptin (3% vs 10%,, p=0,0013) (Fig2).

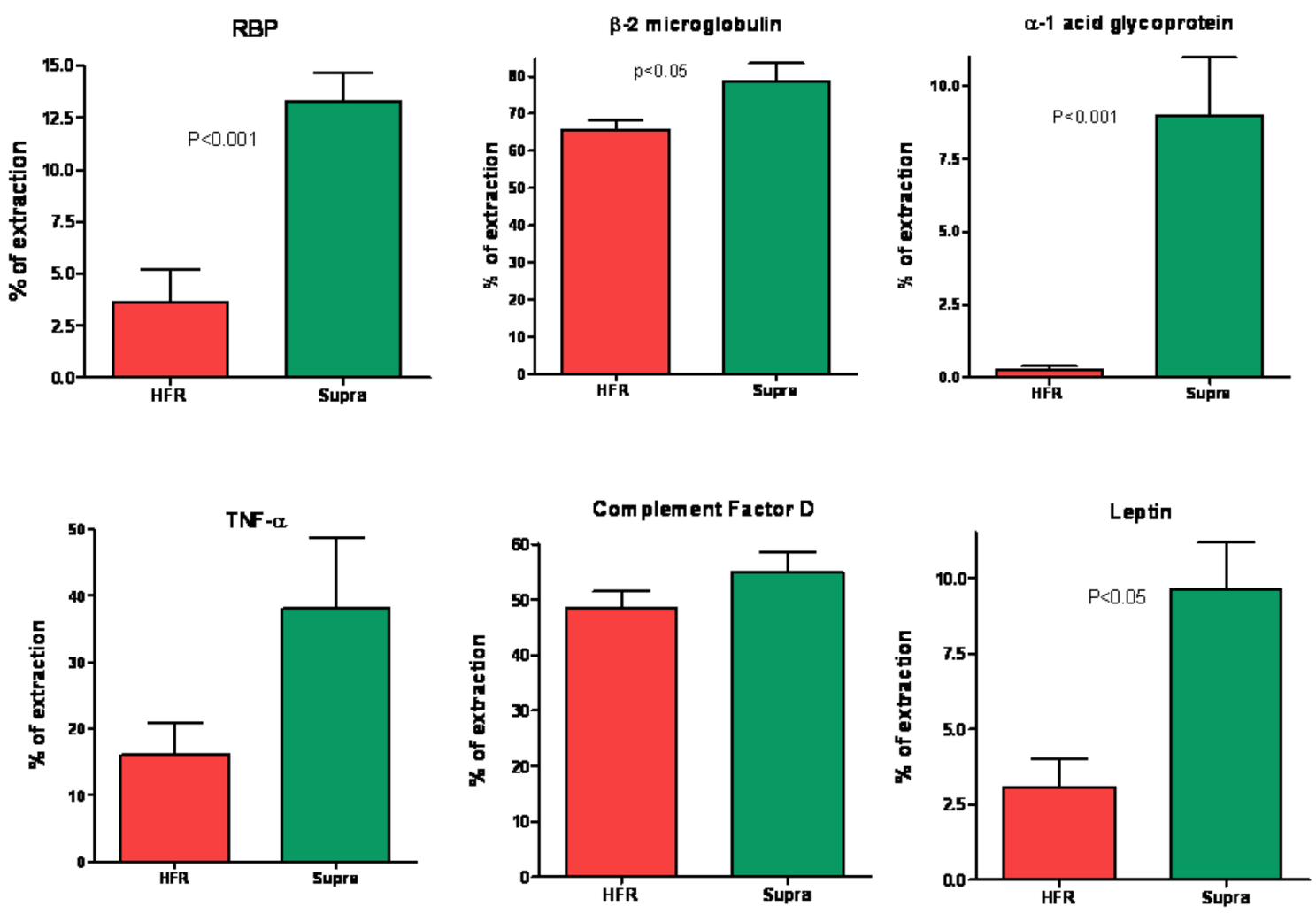

Fig2. Percentage of extraction of the two different membrane pHF (HFR) and Sync 02 (SUPRA)

CONCLUSIONS

The results of this study demonstrate that, compared to pHF, Sync 02 membrane offers a higher permeability to middle MW uremic toxins.

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