# LACK OF CORRELATION BETWEEN DIALYZER ALBUMIN SIEVING COEFFICIENTS AND IN VIVO ALBUMIN REMOVAL IN HEMODIALYSIS AND HEMODIAFILTRATION



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# Background

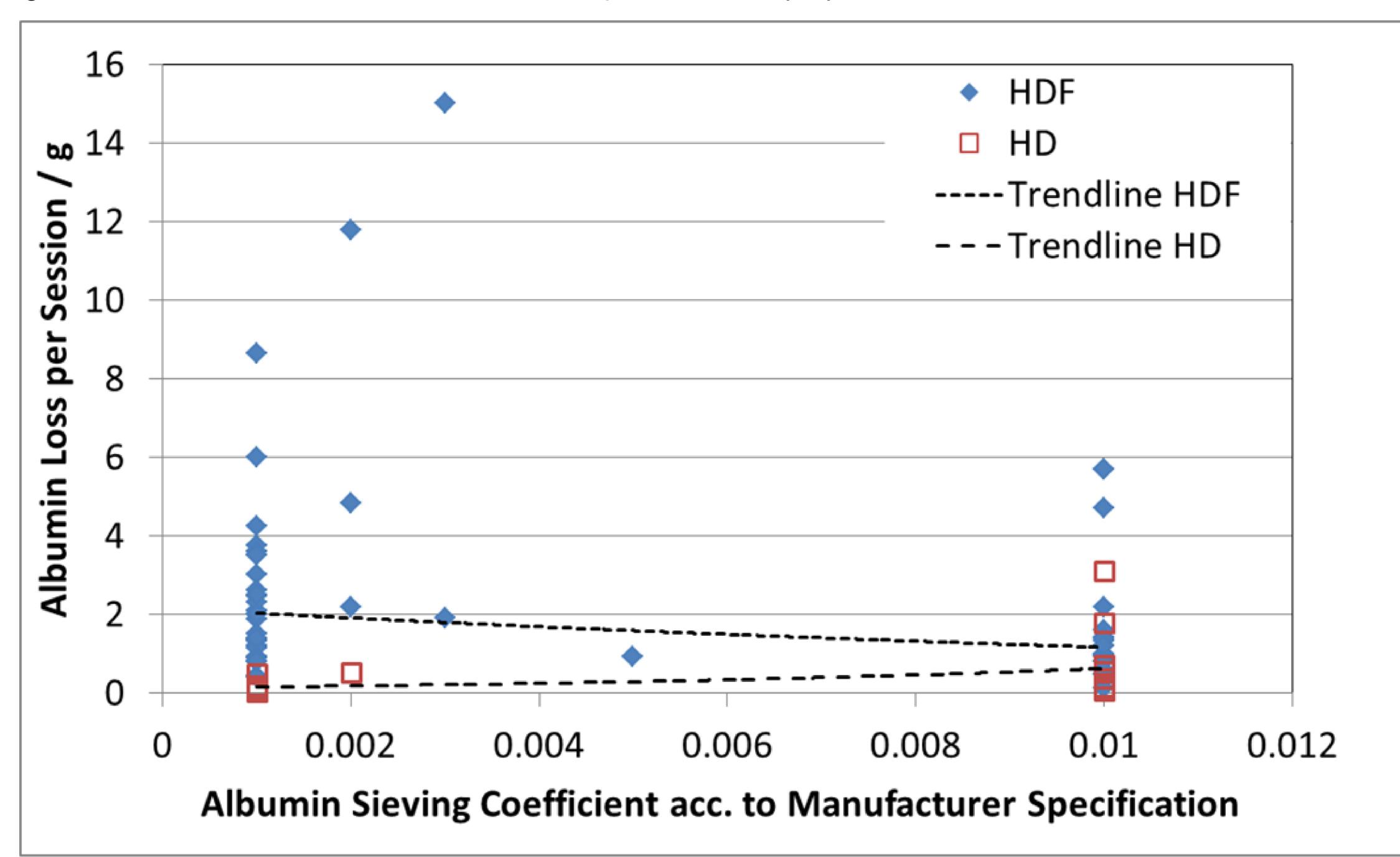
Choice of dialyzers is often based on data provided with technical data sheets and instructions for use (IFUs). Sieving coefficient data displayed in these documents reflect in vitro device testing according to international standards such as ISO 8637. These standards provide guidance on testing procedures, while allowing experimental conditions to vary to a certain extent, e.g. test medium, flow rates, among other parameters. This might possibly hamper direct comparability of the data provided by different manufacturers for their products and limit their usefulness to predict clinical performance, e.g. albumin removal as a clinically relevant parameter (see abstract/poster SP468).

# **Methods**

We hypothesized that comparison of dialyzers, if solely based on technical specifications, might not necessarily reflect their ranking when it comes to albumin removal in the clinical setting. We performed a systematic review of clinical study data, published between 2002 and 2016, on albumin removal during treatment (loss in g per session; mean values as presented in the publication) of a broad range of high flux dialyzers, used in hemodialysis (HD) or post-dilution hemodiafiltration (HDF) (total UF volume  $\geq$  15L or infusion volume  $\geq$  14L), and plotted them vs albumin sieving coefficients taken from manufacturers' specifications for the dialyzers used in the clinical studies. Regression analysis was performed using Excel analysis tool.

### **Results**

We identified eleven publications on HD treatment mode (Ref. 1-11; treatment time 199 to 240 min) and eighteen on post-dilution HDF (Ref. 8-25; treatment time 224 to 294 min, infusion volume 14.4 to 27.9L or ultrafiltration volume 20.1 to 29.9L) that reported clinical albumin removal data for various dialyzer types (9 in HD and 23 in HDF), for which sieving coefficient data were available from manufacturer's data sheets or IFUs. In vitro sieving coefficients given as "smaller than" were considered as "equal to" for the purpose of the correlation.



As depicted in the figure, at the same sieving coefficient, clinical albumin losses were highly variable. Albumin sieving coefficients provided by manufacturers did not show a good correlation with clinical data, i.e. correlation coefficient was  $R^2 = 0.3157$  for HD data and  $R^2 = 0.0888$  for HDF data. A possible explanation for this lack of correlation is that apart from the membrane and dialyzer characteristics (such as membrane porosity, material, device design etc.), albumin loss is likely affected by variations of therapy parameters, e.g. ultrafiltration volume and rate, treatment time etc and possibly patient-related factors that influence blood viscosity. In addition, clinical albumin loss data may also depend on the methods of dialysate collection (Ref. 26) and albumin analysis.

### Conclusions

Clinicians and decision makers at hospitals and dialysis units aim at providing highest quality treatment to their dialysis patients. Our findings demonstrate that, to fulfill this purpose, it might not be sufficient to look at technical data of a dialyzer, which can be impacted by certain method variations despite standardization, but in addition take into account available information on clinical performance.

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