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Letter to Editor

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Problems with acidification of dialysis fluid with 3mmol/l acetate

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Letter to editor

In 1929 Homer W. Smith had written in his Book ("From Fish to Philosopher") the evolution from the fish to the mammals the development of circulation, breathing, buffering and acidification. So the Body Fluid is a Small Primary Sea, which is kept constant by the Kidney. And to transport CO_2 (Carbon-Dioxide), this is transformed into Bicarbonate, as there is high turnover by the metabolism of mammals and especially of men. So you have the little alkaline actual reaction (pH) like in the original Primary Sea with the Acidification of pCO_2 of 40mm Hg (= 1,2mmol/l). This small concentration of CO_2 Gas is important to prevent Calcification of Ions of Calcium and Magnesium with Carbonate.

In the Long-Run of Dialysis the way of Acidification had changed several times. The basic problem was always the same: The treatment time per week was short in comparison the one week living (= 168 hours). So the concentration of the Buffer Bicarbonate in the Dialysis Fluid was set to 32mmol/l (instead of 24mmol/l Bicarbonate in healthy man). Kolff had used Acid Sodium Phosphate. Alwall had used carbogen Gas (5% CO_2). With both Set-Ups there was Calcification, as the amount of Acidification was too low.

In 1965 Acetate Dialysis was introduced (Shaldon and Mion). Acetate was a Buffer Precursor, as the actual reaction (ph) was far distant from its pK value. So this Buffer Precursor must be transformed by passing the liver into Bicarbonate and CO_2. So in the first hour of an Acetate Dialysis, the Patient became more acidotic, as his own Bicarbonate was dialyzed. And after one hour, the liver had transformed the first part of Acetate into Bicarbonate and CO_2. This development was a great success, as it was the begin of the Home-Dialysis and technical with the Single Pass Dialysis. With this Set-Up there was no Calcification. And there were also no further pyrogenic reactions because Bicarbonate in Containers often favors Bacterial Growth.

In 1978 the Bicarbonate Dialysis of today had developed. Because of the Calcification of Bicarbonate a Second Pump for Bicarbonate was installed. The first Concentration Pump of a Fluid System of a Dialysis Generator added all other Electrolytes with the Acidification to the softened water. And then Bicarbonate was added by the Second Pump. These fluid systems for a Dialysis generator were building either in a Mechanical Fixed System of as a Servo System triggered by the Conductivity.

According to the Acidification most Patients are treated up today with 3mmol/l Acetate. In France and Japan higher concentrations of Acetate are used with the result of pCO_2 pressures of more than 120mm Hg. So these elevated pCO_2 Pressures are limitations for COLD Patients as well as for ventilated Patients treated for weaning. And the other hand the Acidification with 3mmol/l Acetate is not sufficient to prevent calcification of Dialysis Fluid. And with online-HDF or online-HF big volumes of the classical Dialysis Fluid with a Calcification Problem run into chronic RRT Patients with their own problem of Calcification. That's why that the Dialysis Monitor descaled after each Dialysis Treatment. But for the Patient there is no descaling.

The big mortality of RRT Patients is well known. This is a context of Calcification of Coronary Vessels and of Heart Valves. Since April 2012 there is a new prescription of Dialysis Fluid on the market with 1mmol/l Citrate. Citric Acid is a threefold Acid, so there are the same mequ/l in it as in 3mmol/l Acetate. And so there is the same CO_2 Production as with 3mmol/l Acetate. But the Citrate Acidification has a second working principle. This is the Chelate Binding of Calcium- and Magnesium-Ions. So both Ions with critical Solubility Facilities are present for the equilibrium, on the other hand these are disguised for Calcification. With this 1mmol/l Citrate Acidification there is absolute no Calcification by the Dialysis Fluid at all, nether in the Dialysis Monitor nor in the Patient.

You can see the Transparency of a Fluid with your own eyes. So you will fill a syringe at first with Saline 0,9%. You can watch the scale of the Syringe through the fluid on the opposite side of it without difficulties. When you repeat this with regular Bicarbonate Dialysis Fluid (with 3mmol/l Acetate Acidification), you will see a cloudy fluid. With this the recognition of the scale of the opposite side of the syringe is by far not so clear. When you take Dialysis Fluid with Citrate Acidification you have the full Transparency through this fluid.

When working with Dialysis Fluid with 1mmol/l Citrate Acidification, the Calcium Concentration of it should be elevated a little, as a small part of Citric Acid will bind a part of Patient's Calcium. This is to prevent a Hypo-Calcemia. By this, you have also an anticoagulatic effect by this form of Acidification. So you can reduce the regular dosage of anticoagulation to 50% without any problem (>Bolus dosage as well as the continuous dosage).

Dialysis Fluid as well as its components are Medical Products. And so this is allowed e.g. by a CE Mark of the Producer. The context of Acidification and Calcification is not well understood by Nephrologists as they are no Chemists. So it seems that in the production of a Medical Product is everything allowed.

I had sent my critics concerning the solubility of Dialysis Fluid with Acidification with 3mmol/l to the BfArM Institute in Germany in October 2012. This is the supervising Authority for Medical Product in Germany. The Result? I received a Reference Number. Then they asked to send this context to a Medical Society (>e.g. DGN, German Nephrologic Society). But this is congregation of Medical Doctors (here: Nephrologists) with only small Chemical Knowledge of solubility. So the transfer to a Medical Society was not my interest, as this is a problem of solubility that needs a Chemist for Evaluation. A second letter by a Medical Lawyer could also not make the BfArM working (!). Even a Letter to the German Minister of Health had no effective output (!). As the BfArM Institute is utterly unable to this serious responsibility, I addressed this problem to the FDA Department of Medical Products in order to reach the necessary Chemical Evaluation.

Conclusion

There is no need to continue with Dialysis Fluid with 3mmol/l Acetate Acidification as there is an alternative prescription (1mmol/l Citrate Acidification) available without any problems of Calcification. So the FDA is asked as first target for a Chemical Evaluation. Second Target will be the Prohibition of Dialysis Fluid with 3mmol/l Acetate Acidification in order to prevent dangerous Therapy.

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Conflict of interest

The author declares no conflict of interest.

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