

# Shortcoming and Gravity of the usual Prescription for Bicarbonate Dialysis Fluid (> Problem of Calcification by Acidification with 3 mmol/l Acetate)

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**This Theme is of far-reaching importance for the Performance of Dialysis and for the Patient's Care - and nothing has changed in-between (!). The Facts of this Case and the Medical Back-Round will explain in the following:**

## Starting Point

Hemodialysis is a Treatment for CKD-5 Patients. So with this therapy RRT-Patients were treated with up to 130 Litres of calcifying Dialysis Fluid. And this Fluid does come in contact with the Patients. Thrice a week these are per year up to 20 m<sup>3</sup>, up to the mode of Treatment (> online-Therapy) even as Infusion.

Central Argument is, that the Quality of Dialysis Fluid has to full-fill highest demands concerning purity (> see ISO-Norm 11663-2009) and composition.

The circulation of Dialysis Fluid starts with the Water Preparation. So there is Descaling and Reverse-Osmosis and Ultrafiltration (of the softened water) at the Monitor. The Monitor will add all requested Electrolyts including the buffer Bicarbonate and the two heavy soluble ions Calcium and Magnesium using Dialysis Concentrate, a Medical Product.

The Dialysis Fluid does contain - as written down - the three following ions with heavy solubility: Bicarbonate, Calcium and Magnesium. In order to prevent the Calcification to Calcium-Carbonate and to Magnesium-Carbonate, there will be added 3,0mmol/l Acetate for Acidification.

## Formulation of the Problem

Our Client is a Nephrologist with long-term experience since four decades. So the problems of Calcification (Coronary Vessels and Heart Valves) are well known.

In his letter to your Institute (dated October 18th 2012) our client had written down his doubts concerning this Prescription of the Classical Dialysis Fluid (> with Acidification with 3 mmol/l Acetate) and complained about the **Insufficient Chemical Solubility**. So the Dialysis Monitor must be descaled after each treatment because of Calcification(!). Only the Patient will not be descaled . . . - When using online-Therapy (online-HDF of online-HF) there are big volumes of this fluid, these will

be infused directly in the Patient **with this Critical Solubility**. Using High-Flux Hemodialysis (the most used mode of Dialysis Treatment) this Critical Fluid will be infused by Back-Filtration into the Patients.

As pointed out in the Letter of October 18th 2012, the RRT Patients have their own big Problem of Calcification even without Dialysis. And this will be enlarged with a lasting effect. And so the Classical Dialysis Fluid (> Acidification with 3 mmol/l Acetate) is an extreme burden for the longer-living concept for the RRT Patients.

**Background:** Patients in state of CKD-IV have their own problem with Calcification. Because of this, there is the severe Over-Mortality by Calcification of Coronary Vessels and Heart Valves - even without any Dialysis Therapy. When the Dialysis is added, then the problem of Calcification increased, as these Patients will enlarge their problems of Calcification by the insufficient prescription of the Dialysis Fluid (> Acidification with 3 mmol/l Acetate).

**Conclusion:** The demonstrated faults of this Prescription of the A-Component with 3 mmol/l Acetate Acidification is unsuitable for the Treatment of RRT Patients, as this cohort of Patient's has his own problems of Calcification. I bring this to one clear point: Only Clear Solutions are allowed to be infused into Patients! The discussed Medical Product is an incompatible Solution concerning Calcification.

Our Client has done a Lecture with this Theme in May 3rd 2013 (Erfurt, Germany, "Afternoon for Engineers"). He will present another Lecture of this Theme in the end of June 2014 in Valencia / Spain (> listeners Medical Doctors).

## Consequences

The duty of BfArM is official but involved into the Authority of the Ministry for Health (BMG) with autonomy. So the

laws of Medical Products (MPG) and the decree for Security of a Medical Product are to respect.

Because of this we assume, that a new evaluation of these realities under these demonstrated circumstances is urgently necessary (here: all A-Components for Dialysis Fluid for Bicarbonate containing Dialysis Fluid with 3 mmol/l Acetate Acidification). As the Dialysis Fluid is a Medical product, is urgently a new evaluation necessary. This has to be done currently(!).

If it is not possible to follow the requests of our client, who had no personal advantage in this case, or if you refuse the Evaluation by a Chemist, then further extensions will be unavoidable. In this case we will inform the German Minister for Health Mr. Hermann Gröhe to do the right things.

**Ultimately this deals of the Defence and Waiver of a considerable Medical Risk. This is connected by the not qualified use of the Classical Dialysis Fluid.** The prescription of the 3 mmol/l Acetate Acidification is very critical to judge, as this gives rise to the additional Calcification for the RRT Patients.

As pointed out clearly, the Evaluation of a Chemist is absolutely necessary. Additionally we ask you to request relevant Information from the Producers of this Dialysis Fluid concerning Calcification.

This includes also the Evaluation to perform the Acidification of Dialysis Fluid in another way. Since April 2012

there is another Acidification with 1 mmol/l Citric Acid available (= equi-molar, as Citric Acid is a three-fold Acid). With Citric Acid the problematic ions (Ca<sup>++</sup> and Mg<sup>++</sup>) are disguised in a Chelate Lattice in order to prevent Calcification. So there is **no need for dangerous Therapy** (with Acidification with 3 mmol/l Acetate). So the Treatment of Dialysis will be well-tolerated, as well as long-term complications (> Calcification) will be reduced and longer-living is not shortened by avoidable additional Calcification.

So today there is the Option of Acidification with Citric Acid.

These remarks show, that the Evaluation of a Chemist is goal-directed, as he is capable to compare the additional Chelate Binding of Citric Acid with the Acetate Acidification.

## References

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