Sohag University

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Association of ultrafiltration rates and intradialytic hypotension in Sohag University Hospitals

Protocol

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Introduction

Chronic kidney disease (CKD) is a significant global public health concern that often leads to end-stage renal disease (ESRD), requiring replacement therapy with haemodialysis or kidney transplantation, associated with increased morbidity and all cause mortality.(1)

Multiple factors contribute to the higher mortality in ESRD, including adverse effects of the dialysis procedure itself. Hypotension during haemodialysis (HD) is of particular importance and one of the most clinically significant complications that may occur during maintenance haemodialysis.(1)

The National Kidney Foundation Disease Outcomes and Quality Initiative (KDOQI) defined IDH as either a decrease in SBP ≥20 mm Hg or mean arterial blood pressure ≥10 mm Hg in conjunction with symptoms of hypotension as vomiting, dizziness and muscle cramps and requirement for intervention. This was followed by the European Best Practice Guidelines, which defined IDH as a decrease in SBP ≥20 mm Hg in combination with associated clinical and nursing interventions. (2)

In practice, the standard IDH definition had not been established, which contributes to the variety in the reported incidence from 7% to 40% among literature.(3)

IDH increases patient mortality by affecting the circulatory and cardiovascular systems. For the short-term, IDH might result in discomfort and inadequate dialysis, contributing to an early end of the dialysis session that affects the patient's quality of life. While for the long-term, IDH could lead to cardiovascular complications, more hospitalization, and all-cause mortality.(4)

Studies report patients with IDH are at higher risk of myocardial ischaemia and that frequent episodes of IDH could lead to vascular access thrombosis in both arteriovenous fistulas and arteriovenous grafts.(5)

Many factors have been reported to be associated with IDH such as age, diabetes,coronary artery disease, residual renal function, pre-dialysis blood pressure, and serum albumin level. (6,7)

Other factors include dialysis factors such as sodium dialysate , calcium dialysate, dialysate temperature, dialytic age, dialysis day, and most importantly ultrafiltration rate (UFR) that plays a crucial role in IDH.(8)

Numerous preventive interventions have been developed and practiced worldwide such as decreasing the temperature of dialysate, increasing dialysate sodium

concentrations or using dialysate with high levels of calcium. However, the standard recommendation for IDH prevention has not yet been settled.(9,10)

Excessive fluid gains between HD sessions will lead to volume overload and increase the risk of mortality in ESRD.In tropical countries with hot and humid weather, patient's adherence to water restriction remains a critical problem.(11)

Although IDWG is associated with a relatively modest increase in plasma volume, most of the combined salt and water fluid gain is sequestered in the extravascular and extracellular spaces. During dialysis, net fluid removal reduces the central filling pressure and leads to a decrease in cardiac output.(12)

High IDWG requires higher UFR, which can overwhelm the physiological compensatory mechanisms and increase the risk of IDH. Even lower UFR can induce IDH in diabetic patients due to slow plasma refill and decreased vasoconstriction secondary to autonomic dysfunction.(12)

In general,starting UF at a higher rate and then slowly decreasing it over the course of the dialysis session is associated with the lower risk of IDH.(13)

Optimal adjustment of the UFR by limiting the rate to the appropriate levels in each haemodialysis session could reduce the risk of IDH, given that the circulation is not severely affected. Few studies regarding UFR adjustment, and its role in IDH prevention have been done. Some studies have reported the impact of different UFR on patient mortality. (13)

United States suggested the UFR <13 ml/kg/h is effective at reducing IDH and its sequelae. However, most of the research was done in western countries with differences in environmental and demographic factors.(14)

The recommended UFR from these studies might not be generalizable to other settings, such as in the tropics.

Aim of the the work

We aim to identify the optimal threshold of ultrafiltration rate to prevent occurance of intradialytic hypotension.

Patients And Methods

- Type of The study:
  A Prospective observational study.

- Place of the study:
  Haemodialysis unit, Sohag University Hospitals,Egypt.

- Patients:

Inclusion criteria:

- All patients aged 18 Year or older on maintenance haemodialysis for at least 3 consecutive months receiving 3 sessions weekly.

Exclusion criteria:

- Patients aged < 18 years old.
- Patients on recent haemodialysis < 3 months.
- Pregnant women.
- Patients with malignancy, severe infections or sepsis.
- Patients with major bleeding.
- Patients who cannot go upper limb monitoring of blood pressure.
- Patients with severe heart failure (NYHA) class 3 or more.
- Patients with severe anemia, Hemoglobin less than 6 g/dl.

Number of Patients:

- The study will include 50 haemodialysis patients for duration of 6 months.

- Methods:

Patients included in the study dialyzed for 4 hours thrice weekly with the Fresenius 4008S (Fresenius medical care, St. Wendel, Germany), using bicarbonate dialysis.

Low molecular heparin or heparin-free dialysis (with periodic tube wash with saline) were selected as anticoagulation methods.

The dialysate composition was: Sodium 135–140 mmol/L, potassium 2 mmol/L, calcium 1.5 mmol/L, bicarbonate 32 mmol/L, acetate 3 mmol/L, glucose 1 g/L , Magnesium ,5 mmol/l, Chloride 111 mmol/L.

UFR will be determined by the constant UFR (ml/h) of each haemodialysis session before any occurrence of the IDH event.

The unit of UFR is converted to ml/kg/h using an individual target body weight.

All haemodialysis session records will be categorized into IDH (case sessions) and non-IDH (control sessions).Then we calculate the IDH proportion (prevalence) for each patient.

The justification of IDH is based on the criterion defined by the European Best Practice Guideline (EBPG),which is a drop in systolic blood pressure of ≥20 mmHg during haemodialysis session and the presence of any associated symptoms of hypotension.

Blood pressure will be measured before and after each dialysis session, as well as every hour during the session. Mean arterial pressure (MAP) will be calculated.

These predictors will be included gender, age, anuric status, diabetes, hypertension, cardiovascular disease, body mass index (BMI), systolic and diastolic blood pressure (pre-dialysis), dialysis vintage, number of Antihypertensive drugs, haemoglobin, albumin level, haemodialysis time of day, haemodialysis day of the week,interdialytic weight gain.

For identification of the appropriate UFR cut-points, UFR will be classified in five subcategories to demonstrate the dose–response relationship of increasing UFR and the IDH occurrence.

- Ethical consideration:

Informed Written consent will be taken from all patients to include their data in the study, the research will be approved by medical ethics committee of Sohag university, Faculty of Medicine.

Statistical analysis

- All collected data will be analyzed and correlated.
- All the statistical analysis will be done by using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL) version20.
- Baseline data and patient characteristics will be presented using descriptive statistics, for example, number, percentage, mean and standard deviation.

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