The incidence, risk factors and outcomes of electrolytes disturbances in critically ill Egyptian Patients: A single-Centre Prospective Cohort Study

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Title of the Protocol:

The incidence, risk factors and outcomes of electrolytes disturbances in critically ill Egyptian Patients: A single-Centre Prospective Cohort Study

Postgraduate Student: **Michael Mamdouh Anwar**
Degree: M.B.B.Ch., M.Sc. Ain Shams University.

DIRECTOR: **Prof. Alaa Eid Mohammed**
Academic Position: Professor.
Department: Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

Co-DIRECTOR: **Prof. Hanaa Mohamed Abdallah EL Gendy**
Academic Position: Professor.
Department: Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

Co-DIRECTOR: **Dr. Doaa Mohammed Kamal EL-Din**
Academic Position: Lecturer.
Department: Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

Co-DIRECTOR: **Dr. Eman Mohamed Hesham Khalyl EL-Shaer**
Academic Position: Lecturer.
Department: Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

Faculty of Medicine - Ain Shams University

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What is already known on this subject?

Electrolytes disorders are common in hospitalized patients and associated with increased morbidity and mortality. The combination of metabolic acidosis plus respiratory acidosis often occurs in critically ill patients with cardiac arrest, renal failure and severe congestive heart failure.

1. INTRODUCTION:

Electrolytes imbalance (EI) is common in hospitalized patients as well as in the general population and is associated with increased morbidity and mortality [1–9]. Clinically important EIs include dysnatremia, dyskalemia, dyscalcemia, dysmagnesemia, and dysphosphatemia.

Electrolyte disorders are defined as an altered level of the following at least one of the electrolytes (potassium, chloride, sodium, or calcium level, magnesium and phosphorus), that is, either increasing or decreasing from the normal range. The following ranges are used to determine the imbalance for each electrolyte: Na+= 135-145 mmol/L, K+= 3.5-5.5 mmol/L, Ca2+ = 2.1-2.55 mmol/L, and Cl− = 98-108 mmol/L, Mg+2 = 1.6-2.5 mg/dl, PO4- = 1.12-1.45 mg/dl. [10]

EIs have previously been investigated in several different cohorts. However, most previous studies have investigated one or two specific electrolytes in a selected group of patients with a single disease (e.g., heart or kidney disease) [11 - 13], or in patients in a particular risk group (e.g., intensive care patients or patients using diuretics).

In recent years, however, it has become clear that chronic and mild electrolyte disorders also are associated with adverse outcomes, including in the general population.[1] Because of these emerging insights, it is important to know the exact prevalence and risk factors of electrolyte disorders in the general population. Mild electrolyte disorders are common in the general population aged 55 years or more (15%). Risk factors for electrolyte disorders in the general population are similar to those in hospitalized patients, including diabetes mellitus and all types of diuretics.

2. OBJECTIVES:

The aim of this study is to determine the incidence and risk factors of common electrolyte disorders in critically ill Egyptian people.

3. METHODOLOGY:
Patients and Methods:

- **Type of Study:** A single-centre prospective cohort study
- **Study Setting and ethical consideration:** The approval of the Scientific Research

Ethics Committee of the Faculty of Medicine, Ain Shams University will be obtained before starting work on the study.

- **Study Period:** One year (2023-2024)
- **Study Population:** critically ill Egyptian patients
- **Selection criteria for cases:**
  - ***Inclusion Criteria:***

All patients admitted to medical ICU, surgical ICU and CCU suffering from electrolyte imbalance (EI) over 18 years with the comorbid conditions like (hypertension, heart failure, chronic chest diseases, cancer, chronic kidney disease, diabetes mellitus, cardiac dysrhythmias, pneumonia, sepsis, dehydration, and critical bones fractures, etc.)

  - ***Exclusion criteria:***

Patients with

1. Age less than 18 year old
2. Patient or his 1st degree relatives refuse to participate
3. Patients without electrolytes data
4. Current smoking

- **Ethical Considerations:**
  1. Informed and written consent
  2. Patient information sheet
  3. Confidentiality
  4. Privacy
  5. Respect & responsibility
- **Sample Size:** Using the PASS 15 program for sample size calculation, reviewing results from the previous relevant study (Ibrahim et al,2022) showed that the incidence of hypokalemia was 80.5%, with a margin of error =10% and 95% confidence level and after a 10% adjustment for dropout rate a sample size of at least 110 patients will be needed.
- **Study Procedures:** All selected individuals will be suffering from electrolyte imbalance (EI) with the following data will be obtained:
  - ***Measurements:***

1) Demographic data: age - gender – BMI - electrolytes data on ICU admission

2) Vital data: heart rate – respiratory rate – blood pressure measurement – Oxygen saturation – Urinary output – Temp +/- CVP measurement.

3) Lab.: "CBC – Kidney function tests – liver function tests – ABG – levels of serum sodium, potassium, magnesium, phosphorus, ionized calcium and chloride", with maximum 5 mm blood sampling per day. Serum-sodium levels will be corrected for serum-glucose by lowering the sodium concentration by 2.4 mmol/L for every 100 mg/dl increase in glucose.

Corrected Sodium = Measured sodium + 0.016 (Serum glucose - 100) [14]

A correction formula was also used to calculate albumin-corrected calcium levels (mmol/L)

Corrected Calcium = (0.8 (Normal Albumin - Pt's Albumin)) + Serum Ca [15]

4) APACHE II score

5) Comorbidities

6) Complications: AKI- Acute myocardial infarction

7) Duration of ICU stay

8) Duration of hospital stay

9) Outcome (regarding eventual complications: AKI- Acute myocardial infarction)

- **Study Interventions:**

<u>All selected individuals will be subjected to the following:</u>

1) Full medical history taking

2) Full clinical examination, APACHE II score on admission

3) Electrolytes pannel daily on ICU admission

4) Estimate the duration of stay at ICU

Also all selected individuals will be sectioned into groups regarding sites of collection (surgical ICU, CCU and medical ICU).

All collected individuals will be sectioned regarding electrolytes imbalance into mild, moderate and severe groups [16].

- **Statistical package and Analysis:**

The collected data will be revised, coded and introduced to a PC using statistical package for social science (SPSS 15.0.1. for windows; SPSS Inc, Chicago, IL, 2001).

Data will be presented as mean and standard deviation (+- SD) for quantitative prometric data. Suitable analysis will be done according to the type of data obtained. P< 0.05 will be considered significant.

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