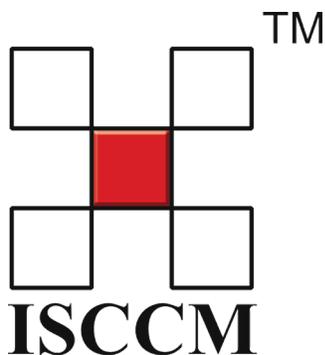


**Salt based Or baLanced solUtion.
Trends Existing in Indian intensive
care units. A multicenter prospective
observational cohort study (SOLUTE
study)**

An ISCCM Research Project



Principal Investigator:

Dr Sachin Gupta

Narayana Superspeciality Hospital, Gurgaon, India

Email: dr_sachin78@yahoo.co.in, Ph: 9873240734

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INTRODUCTION

The intravenous fluid administration is probably the most common intervention that one does in intensive care units (ICU) to increase the intravascular volume. The existing literature favors the use of crystalloids over colloids but within crystalloid the choice is still controversial.

Worldwide, 0.9% sodium chloride also known as normal saline (NS) remains the most preferred resuscitation fluid¹.

The use of NS has been associated with hyperchloremic metabolic acidosis² and sometimes with acute kidney injury (AKI)³. Nowadays, the practice is shifting towards using crystalloids having compositions similar to that of plasma, known as balanced solutions⁴. Many of the observational studies and other trials have suggested that use of balanced solution is associated with reduced incidence of AKI, renal replacement therapy (RRT) and eventually death. However, the recent SMART trial⁵ could not find any such difference.

Till date there has been no data about the practice of fluid administration in Indian ICUs. We would like to collect data prospectively from various ICUs across the country regarding the nature of fluid administration both as boluses and as maintenance fluids. We would conduct this study over 8-month period. We want to compare normal saline with balanced crystalloids for incidence of AKI, need for RRT and overall outcome of the patients over a 28-day follow up period.

OBJECTIVES:

- To capture data on the practice of fluid administration in critically ill patient
- To identify any possible relationship between incidence of new onset acute kidney injury with the type of intravenous fluid administered
- To compare normal saline with balanced crystalloid on renal outcomes and survival outcome

METHODS:

Study design:

- Prospective Observational Multi-Centre National Cohort Study

Patient enrollment:

The study would invite all ICUs across the country to participate in the study. The invites will be sent at frequent intervals by the ISCCM office through emails. Hospitals with more than one ICU can enroll each ICU separately. Each ICU can contribute as much data as possible during the study period. Each ICU will designate one PI and one co-PI for the study who will be responsible for ethical committee clearance (if required), data collection and study co-ordination in their ICU. Each ICU will collect data from 1st May to 31st December. The study would end on 28th January 2021 when the final outcome data will be entered.

Each centre can start recording the data in paper CRF till they get an Ethics approval (if required) and later on can fill the data online.

Study timelines:

Email invitation to all ICUs: **20th May 2020**

Start of data collection: **1st June 2020**

Last date of data collection: **31st December 2020**

Last date of data entry: **28th January 2021**

Data cleaning and analysis: **Uptil 15th February 2021**

Presentation in CRITICARE 2021: **February 2021**

Publication: **2021**

Inclusion Criteria:

- All adult patients (> 18years old) admitted to ICU receiving intravenous fluid administration as per their clinical condition

Exclusion Criteria:

- Patients on renal replacement therapy for end stage renal disease
- Patients expected to undergo or who undergo renal replacement therapy within 6 hours of ICU admission

Data Collection:

There will be no direct patient contact or change in intervention. The fluid administration will be given as per the physician guided protocol or any other protocol existing in the respective ICU. There will be no change in the prevailing practice of ICU. The data will be collected prospectively and filled in the Case Record Form (CRF). The fluid administered will be recorded as bolus (if more than 5ml/kg/hr has been administered within one hour), maintenance (the fluid which is given continuously to meet the daily fluid requirement) and as replacement (fluid which is given for replacement of losses like drain losses, gastric tube losses or given as dilution for antibiotics and other medications)

The following data will be collected:

- **Baseline characteristics** – age, gender, weight, co-morbidities, source of ICU admission, diagnosis at the time of admission, APACHE II & SOFA score on ICU admission, baseline serum creatinine
- **Intervention details** – Fluid administered in last 24 hours before ICU admission, first three days’ details of fluid administration, urine output, fluid balance, laboratory values, arterial blood gases, daily SOFA scores and evidence of Sepsis as per SEPSIS-3 definition
- **Outcome details** – Need for renal replacement therapy, indications for RRT, renal outcomes as per RIFLE & KDIGO criteria, need for blood transfusion, ICU & Hospital length of stay, survival status of the patient at or before day 28.

Primary Outcome:

- Comparison of normal saline with balanced crystalloid fluid in incidence of new onset AKI

Secondary outcome:

- Need for renal replacement therapy
- Renal outcome as per RIFLE & KDIGO
- ICU survival status at day 28
- Hospital survival status at day 28

Sample Size:

The plan is to enroll as many ICUs in the country as possible. Each centre will collect data from all consecutive patients being admitted to ICU after ruling out exclusion criteria. An acceptable sample size would be atleast a total of 2000 patients.

STUDY REGISTRATION:

The Principal Investigator (PI) will register the study on CTRI and the registration number would be provided to them once available.

INSTITUTIONAL ETHICS COMMITTEE APPROVAL

All the local PI and Co-PI should ensure that they obtain the necessary Ethics Committee approval for the study, if deemed necessary by the institute. As this is an observational data collection with no intervention, the study can also be approved by the Head of the institute or Medical Superintendent if there is no Ethics Committee in the institute. As per the latest ICMR guidelines, this study falls in minor risk category where it is eligible for ethics exemption or an expedited review by ethics committee.

CONSENT FOR DATA COLLECTION:

This being an observational data collection with no change in the local practice of the institute, the consent is not required from the patient or their legally accepted representative. But if still the institute demands consent, then sample consent forms in Hindi and English will be provided.

STUDY FUNDING:

This is an ISCCM funded study. The ISCCM will fund the PI of the study for the expenses incurred related to software development, secretarial assistance, data analysis and other miscellaneous expenses against actual bills. No funding will be given to other investigators from other centres for contributing the data.

DATA OWNERSHIP:

As this is an ISCCM initiated project, the entire ownership of the data will be with the ISCCM.

PUBLICATION AND AUTHORSHIP POLICY:

The main results of the study will be published in a peer-reviewed medical journal.

The Authorship policy will follow the recommendations laid down by International Committee of Medical Journal Editors (ICMJE). The authorship would be decided on the basis of the contribution in study design, protocol writing, data interpretation and cleaning, data analysis and writing the final manuscript.

Steering Committee: Members would include 2 members from the PIs centre, ISCCM President, ISCCM Past President, President Elect, Research Committee Chairman, and PIs from top 5 centres contributing maximum data. The name of the Steering Committee members will be in the main author list.

The PI and Co PI of all the contributing centres will be included in the list of study collaborators and will be indexed in PubMed.

REFERENCES:

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5. Semler MW, Self WH, Wanderer JP, Ehrenfeld JM, Wang L, Byrne DW, et al. Balanced Crystalloids versus Saline in Critically Ill Adults. *N Engl J Med* 2018;378:829-39.