Sodium bicarbonate therapy for patients with severe metabolic acidaemia in the intensive care unit (BICAR-ICU): a multicentre, open-label, randomised controlled, phase 3 trial

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Résumé en anglais	BACKGROUND: Acute acidaemia is frequently observed during critical illness. Sodium bicarbonate infusion for the treatment of severe metabolic acidaemia is a possible treatment option but remains controversial, as no studies to date have examined its effect on clinical outcomes. Therefore, we aimed to evaluate whether sodium bicarbonate infusion would improve these outcomes in critically ill patients. METHODS: We did a multicentre, open-label, randomised controlled, phase 3 trial. Local investigators screened eligible patients from 26 intensive care units (ICUs) in France. We included adult patients (aged ≥18 years) who were admitted within 48 h to the ICU with severe acidaemia (pH ≤7·20, PaCO ≤45 mm Hg, and sodium bicarbonate concentration ≤20 mmol/L) and with a total Sequential Organ Failure Assessment score of 4 or more or an arterial lactate concentration of 2 mmol/L or more. We randomly assigned patients (1:1), by stratified randomisation with minimisation via a restricted web platform, to receive either no sodium bicarbonate (control group) or 4·2% of intravenous sodium bicarbonate infusion (bicarbonate group) to maintain the arterial pH above 7·30. Our protocol recommended that the volume of each infusion should be within the range of 125-250 mL in 30 min, with a maximum of 1000 mL within 24 h after inclusion. Randomisation criteria were stratified among three prespecified strata: age, sepsis status, and the Acute Kidney Injury Network (AKIN) score. The primary outcome was a composite of death from any cause by day 28 and the presence of at least one organ failure at day 7. All analyses were done on data from the intention-to-treat population, which included all patients who underwent randomisation. This study is registered with ClinicalTrials.gov, number NCT02476253. FINDINGS: Between May 5, 2015, and May 7, 2017, we enrolled 389 patients into the intention-to-treat analysis in the overall population (194 in the control group and 195 in the bicarbonate group). The primary outcome occurred in 138 (71%) of 194 patients in the control group and 128 (66%) of 195 in the bicarbonate group (absolute difference estimate -5·5%, 95% CI -15·2 to 4·2; p=0·24). The Kaplan-Meier method estimate of the probability of survival at day 28 between the control group and bicarbonate group was not significant (46% [95% CI 40-54] vs 55% [49-63]; p=0·09. In the prespecified AKIN stratum of patients with a score of 2 or 3, the Kaplan-Meier method estimate of survival by day 28 between the control group and bicarbonate group was significant (63% [95% CI 52-72] vs 46% [35-55]; p=0·0283). Metabolic alkalosis, hypernatraemia, and hypocalcaemia were observed more frequently in the bicarbonate group than in the control group, with no life-threatening complications reported. INTERPRETATION: In patients with severe metabolic acidaemia, sodium bicarbonate had no effect on the primary composite outcome. However, sodium bicarbonate decreased the primary composite outcome and day 28 mortality in the a-priori defined stratum of patients with acute kidney injury. FUNDING: French Ministry of Health and the Société Française d'Anesthésie Réanimation.
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